MEDICARE PART D: IMPLEMENTATION OF THE NEW DRUG BENEFIT

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

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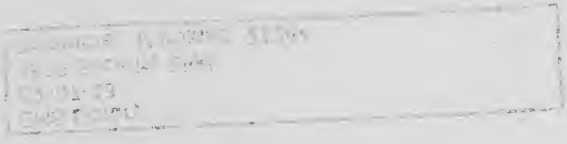

MEDICARE PART D: IMPLEMENTATION OF THE NEW DRUG BENEFIT

WEDNESDAY, MARCH 1, 2006

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:00 p.m., in Room 2123 of the Rayburn House Office Building, Hon. Nathan Deal (chairman) presiding.

Members present: Representatives Deal, Hall, Bilirakis, Gillmor, Norwood, Shimkus, Pickering, Buyer, Pitts, Ferguson, Burgess, Barton (ex officio), Brown, Waxman, Towns, Pallone, Gordon, Rush, Eshoo, Strickland, DeGette, Capps, Allen, Davis, Baldwin, and Dingell (ex officio).

Staff present: Chuck Clapton, Chief Health Counsel; Melissa Bartlett, Counsel; Ryan Long, Counsel; Nandan Kenkeremath, Counsel; Bill O'Brien, Research Assistant; David Rosenfeld, Counsel; Brandon Clark, Policy Coordinator; John Ford, Minority Counsel; Chris Knauer, Minority Investigator; Purvee Kempf, Minority Counsel; Amy Hall, Minority Health Professional Staff Member; Bridgett Taylor, Minority Health Professional Staff Member; Jessica McNiece, Minority Research Assistant; Jonathan Brater, Minority Staff Assistant; and Chad Grant, Legislative Clerk.

MR. DEAL. The meeting will come to order. If someone would get the door in the back, please. The Chair recognizes himself for an opening statement. We are pleased to have Dr. McClellan here as our member of our first panel and another rather distinguished second panel that will follow shortly thereafter. The purpose of the hearing today is to examine the implementation of the new Medicare prescription drug benefit. Today, I believe, marks the sixtieth day of the implementation of the biggest change to Medicare in its 40-year history. Like most significant programs, the new benefit has not gone without a few isolated glitches and unexpected problems, but I believe that if there is anything wrong with the plan, most of it has been fixed and that that hasn't can be fixed over time. In fact, I understand that most of the early glitches in the program have already been resolved thanks to the hard work and cooperation of CMS, pharmacists who are dealing with it on a daily basis, and the prescription drug plans, themselves.

Because of this new benefit, America's senior citizens are better off, and today more than 25 million Medicare beneficiaries are receiving benefits under this new Medicare prescription drug benefit. This includes more than 5.3 million beneficiaries who have signed up individually for prescription drug coverage in the last three months, including 1.5 million who have signed up in the last 30 days.

The new prescription drug benefit is working for American citizens because of the hard work and commitment by pharmacists, physicians, plan employees, public administrators in the States, Dr. McClellan and his staff at CMS. Also, by all the cooperation of family and friends of Medicare beneficiaries who take the time to help their loved ones sign up for the plan and to make the right choices that they think meet their individual needs.

I talked with constituents in my district and many of them tell me that before the implementation of this benefit, they were spending several hundred dollars out of their own pocket on prescription drugs. Many times it was equal to, and in some cases even exceeding, their Social Security benefits. Today, many of these constituents are now spending less than $100 a month thanks to this new prescription drug benefit. Many of them tell me that sometimes the money they didn't have for drugs, they had to put on credit cards or ask family members to assist in paying for those benefits, and by having this benefit available it has restored their personal dignity.

Anything that you try to do is going to have objectors, and we have certainly had our share of objectors, and we will hear some of those objections, I am sure, here today. Many of us have held town hall meetings across our districts and have provided assistance in enrolling seniors into programs. Others have not been quite so cooperative in that effort, but many of my colleagues on this committee have done exactly that -- both Democrats and Republicans. I thank them for that, because I think it is our obligation to assist seniors in making this benefit package work for them.

I want to thank our expert panel of witnesses for taking their time to come and we are going to hear a variety of points of view, obviously, in a panel as large as the second panel will be. I look forward to hearing your testimony. Thank you again and at this time I would recognize the Ranking Member, Mr. Brown.

[The prepared statement of Hon. Nathan Deal follows:]

PREPARED STATEMENT OF THE HON. NATHAN DEAL, CHAIRMAN, SUBCOMMITTEE ON HEALTH

- The Committee will come to order and the Chair recognizes himself for an opening statement.

- The purpose of this hearing is to examine the implementation of the new Medicare prescription drug benefit.
- Today marks the 60th day of the implementation of the biggest change to Medicare in the 40 year history of the program.
- And like most significant new programs, this new benefit has not gone without a few isolated glitches and unexpected problems.
- However, I believe that there isn't anything wrong with the Medicare prescription drug benefit that cannot be fixed with time.
    - In fact, I understand that most of the early glitches in the program have already been resolved thanks to the hard work and cooperation of CMS, pharmacists, and the prescription drug plans.
- Because of this new benefit, America's senior citizens are better off.
- Today, more than 25 million Medicare beneficiaries are now receiving benefits under the new Medicare prescription drug benefit
    - This includes more than 5.3 million beneficiaries who have signed up individually for prescription drug coverage in the last three months, including 1.5 million who signed up in the last 30 days.
- The new prescription drug benefit is working for America's seniors because of the hard work and commitment by
    - Pharmacists
    - Physicians
    - Plan employees
    - Public Administrators in the states
    - Dr. McClellan and his staff at CMS
    - And all the friends and family of Medicare beneficiaries who took the time to make sure their loved ones took advantage of all of the choices in plans and enrolled in the plan that best suits their individual needs
- I talk with constituents all the time in my district that tell me that before the implementation of this benefit, they were spending several hundred dollars out their own pocket on prescription drugs. Many times they were turning over their entire Social Security check to the pharmacist and still not able to buy all the drugs they needed to stay healthy.
    - These same constituents are now spending less than $100 per month on their drugs each month thanks to the new Medicare Prescription Drug Benefit.
    - They tell me how they now have several hundred dollars a month that they didn't have before to spend on things other than drugs and that they are now able to take all the drugs they need without having to borrow money from credit card companies and family members.
    - For many of them, this new benefit has given them their dignity back.
- Unfortunately, as is so often the case, the people who voted against this bill find themselves on the wrong side of history and are now taking advantage of every opportunity to attack this new benefit by seizing on every little temporary glitch and exaggerating often isolated problems and making them seem like the norm.
- Of course, these partisan attacks and political posturing do nothing to help America's seniors.
- In fact, rather than holding town hall meetings to educate beneficiaries about the law and help them pick a plan that best meets their needs, the Democratic Leadership is instructing their Members to hold town hall meetings blasting the benefit.
- How many seniors have they scared away from saving thousands of dollars in drug costs because of their rhetoric?
- How many seniors are having to do without some of the medications they need because of this rhetoric?

- How many seniors are having to go to their family members, swallow their pride, and ask for money for their drugs because of this rhetoric?
- But I want to thank my Democratic colleagues who chose not to go this route and hurt our senior citizens in exchange for some short-term political gain.
- Indeed, many Democrats on this Committee have made the right decision by not going the Pelosi route but instead chose to help their constituents get the most out of this wonderful new benefit by holding educational town hall meetings and helping their seniors enroll in the most appropriate plan for their needs.
    - It is my hope that more of your colleagues will follow your lead.
- I want to thank our expert panel of witnesses for taking the time to testify before us today. I look forward to hearing from each of you.

MR. BROWN. Thank you, Mr. Chairman, and welcome, Dr. McClellan. Nice to see you again. Thank you for joining us. You and I have spoken about and I appreciate your taking my call a couple of weeks ago about the frustration, anxieties they try to navigate, as seniors try to navigate the new drug program. I know you have taken steps to improve customer service at the request of many on both sides of the aisle, this panel and others, and I am grateful for that. Insurers like Anthem in Ohio have been trying to make the best out of a bad situation. I am equally grateful for that. But no one in the Bush Administration, no one in the insurance industry has been willing to acknowledge, much less tackle, the big issues that Medicare Part D has brought. I find that appalling.

When Democrats talk about the problems dragging this program down, we are accused of politicizing the issue. That accusation would carry a lot more weight if we were making a mountain out of a molehill. Instead, the Bush Administration and the Republicans in Congress are trying to make a molehill out of a mountain. The problems with this drug program are real, they are significant, they are ongoing. If someone doesn't take those problems seriously and it doesn't sound like people in this institution are, we have no hope of solving them.

First, there is a looming enrollment deadline. How could it possibly be fair for Medicare beneficiaries to pay a penalty if they don't enroll by May 15th? How can anyone blame seniors if they have been either too perplexed or too wary to enter the fray? I spoke to a Medicaid eldercare lawyer in Butler County, north of Cincinnati, about two months ago who, about a month and a half ago, who told me, as a Medicaid lawyer, that she couldn't figure out this benefit for her mother. And why isn't the Administration working with Congress to extend the enrollment deadline?

It is pretty clear that that is just the tip of the iceberg. The biggest problem with the new drug program is the program, itself. Privatizing prescription drug benefits for seniors never made sense and now it is wreaking havoc. You know and I know that the problems dogging this

program aren't over, they are just beginning. Wait until seniors face prior authorization requirements, driven not by medical necessity, but by the bottom line. Wait until formularies change, premiums change, deductibles change, co-pays change. Wait until drug plans drop out of the program. Wait until seniors learn their neighbors one county over have lower premiums. Wait until seniors who pick the best plan for them on that day need another prescription, one that turns a right plan into the wrong one. And these are just the coverage problems.

The financial issues are equally daunting. Genentech recently announced that it plans to charge $100,000 for a year's worth of the cancer drug, Avastin. The company didn't bother to weave a story to the media about recouping R & D cost, Genentech simply said Avastin will carve the best and will cost $100,000 because that is what the market will bear. The Medicare drug law prohibits the Federal government, amazingly so, we all know this now, prohibits the Federal government from negotiating drug prices. If Genentech wants to arbitrarily charge $100,000 so it can generate billions in profits, why should taxpayers have anything to say about it? Taxpayers contributed $45 million to the development of this drug. Americans are being charged the highest price in the world for that drug and Medicare is not allowed to negotiate a discounted price for that drug. We might as well eliminate the middle man and give the drug industry a vote in Congress and a Cabinet position.

Democrats have introduced legislation to eliminate the prohibition on price negotiations. We have introduced legislation to extend the penalty-free enrollment deadline. We have introduced legislation to rationalize prior authorization rules to dispense with mid-year formulary changes and let seniors switch plans if the initial one turns out to be a lemon. We have introduced legislation that goes back to the basics to enable Medicare beneficiaries to bypass private insurance so they don't spend all their time trying to figure out and compare 40 or 50 insurance company brochures, instead to simply add Medicare prescription drugs to their Medicare benefits package and no confusion, no drama, just a good drug benefit, the way we should have done at the beginning.

Numerous choices have been foisted upon seniors. It is time to give them the one choice they want. I spent the last six weeks traveling Ohio, talking to pharmacists and seniors in Vandalia and Cincinnati and Lima and Bowling Green and Toledo and Akron and Cleveland and Mansfield and Columbus and Youngstown and one drug store, one pharmacist in Norton, Ohio, a suburb of Akron, told me that Congress and the president simply must have handed a blank legal pad to the drug industry and said hey, write this bill for us, would you? It's never pleasant to admit you were wrong, but it is worse to ride a dead horse. I hope my

Republican colleagues will decide it is time to focus on the well being of Medicare beneficiaries and help us make this drug program work. Thank you, Mr. Chairman.

MR. DEAL. The Chair recognizes the Chairman of the full committee, Mr. Barton of Texas.

CHAIRMAN BARTON. Thank you, Mr. Chairman, for holding this hearing. I want to thank Dr. McClellan for once again coming before the subcommittee. It is always good to see a fellow Texan. I am looking forward to hearing your perspectives. We also look forward to hearing the perspectives of the panel that is going to come after you.

Medicare is finally providing patients with prescription drugs after years of false starts, failed attempts. and endless debate. Congress finally delivered on its promise and created a Medicare prescription drug benefit. The result is not perfect. In fact, it is no secret that during those negotiations and markups several years ago, I unsuccessfully sought to make several changes when we debated the Medicare Modernization Act of 2003 in this very room. At the end of the day, however, I voted for the bill, voted for it in committee, voted for it on the floor, and voted for it in conference.

We negotiated a compromise that has created what we now call the program, Medicare Part D. Where our critics before us had failed for 40 years, that Congress and now this Congress has delivered a Medicare prescription drug benefit for millions of senior citizens. We are now in the sixtieth day of this new benefit. Although you wouldn't believe it from some accounts, more than five million seniors have enrolled in the new Medicare prescription drug benefit plan. Another 20 million are getting assistance in existing plans that Medicare is helping to subsidize in some way. That adds up to 25 million seniors, and they are signing up at the rate of about a half a million a week. That sounds like a success to me, not a failure.

The people that are signing up are saving money. Their monthly premiums have dropped from an initial estimate of $37 down to about $25 a month. CMS reports that the plans they are joining are doing better than anybody expected to increase the use of generic drugs and to negotiate deeper discounts with drug manufacturers. The market works. People are making choices and supplies are responding to market competition. This is translated into real savings for Medicare beneficiaries, meaning that they have been able to reduce their drug spending by thousands of dollars on an individual basis on an annual basis.

We are going to hear from some real beneficiaries today, including one from my Congressional district, Mr. Marcus Hickerson, who I can see out in the audience over on, unfortunately for me, on the Democratic

side, that he and his wife are there. Marcus is a long time friend, a civic leader in Waxahachie, and if he says on the record what he has told my staff in private, he is saving about $2,400 this year because of the new Medicare prescription drug benefit. These kinds of savings should not surprise anybody on this committee. Many of us understand that when we give consumers choices and let free markets and competition work, prices fall. This is what we saw with Medicare prescription drug cards; this is what we are beginning to see now with the drug plan, itself.

The critics don't get it. Some of them never will, no matter what the facts are. It appears that the Democratic leadership in the House of Representatives has decided that political advantage may be gained by scaring seniors and discouraging them from enrolling in the new plans. They have recently sent out packets of information to all House Democrats arguing that patients are not smart enough to understand the new benefit. They say the coverage is spotty at best and signing up is not worth beneficiaries' time because it simply cannot save them a dime. They are wrong. They were wrong when they complained about the prescription drug card. They were wrong when they said nobody would offer any plans. They were so very wrong then, and they are just as wrong now, in my opinion. Of course, we are going to have an honest debate about that as this hearing progresses.

As I mentioned earlier, the new benefit and its implementation are hardly perfect. At the same time, I am proud to say that in my Congressional district, 81,000 seniors have been able to take advantage of the new plan. That is 81,000 seniors in the Sixth District of Texas who weren't scared off and who certainly were smart enough to figure it out for themselves. Some may say that my 81,000 constituents have made a mistake. They may say that my constituents should be confused and should be disgusted instead of being pleased at saving the money that they are saving. But I am happy to report that in my district, so far, the seniors are voting with their wallets and their good sense, they are ignoring the bad advice and they are signing up.

Now, 81,000 is a good number, but it is not a perfect number. We can do better. Only about half of my seniors that could sign up have signed up so far. I hope that every Medicare beneficiary who could save some money through this new benefit will take the time between now and the middle of May to look at the program, decide which benefit program most benefits their particular need and does take the opportunity to sign up. I am also going to ask that my Democratic colleagues on this committee really take a look at the plans. Now, there are bound to be some of the plans that help seniors in their districts. They can't be just plans that help seniors in Republican districts.

Rather than trying to scare and confuse seniors, I would hope that we can work together as we go through the implementation phase to find out what is wrong with the program and if we can make some changes to fix it, let us do it and let us do it on a bipartisan basis. We owe that to all of the millions of Medicare beneficiaries. We are going to hold aggressive oversight over the implementation of this plan. It is too big of a program and it is too important to too many people not to do that. But having said that, if it does appear that it is working, let us admit it, you know, let us not keep beating a dead horse.

I want to thank Chairman Deal for calling this hearing, reiterate my thanks to all the witnesses. I look forward to the testimony and look forward to working together to improve this program and implement it in a fair way to all of our senior citizens. Thank you, Mr. Chairman.

[The prepared statement of Hon. Joe Barton follows:]

PREPARED STATEMENT OF THE HON. JOE BARTON, CHAIRMAN, COMMITTEE ON ENERGY AND COMMERCE

Good afternoon. Welcome, Dr. McClellan and all of our other witnesses. I look forward to hearing your perspectives on how the new Medicare drug benefit is being implemented.

Medicare is finally providing patients with prescription drugs. After years of false starts, failed attempts and endless debates, Congress has finally delivered on its promise and created a Medicare prescription drug benefit. The result is not perfect – in fact, it is no secret that I unsuccessfully sought to make several changes when we debated the Medicare Modernization Act in 2003. At the end of the day, however, we negotiated a bipartisan compromise to create the new Part D program. Where our critics had failed for 40 years, we delivered Medicare coverage of prescription drugs.

As we approach the 60th day of this new benefit, more than 5 million Americans have decided to enroll in the new Medicare drug plans. You wouldn't know it from either the news or the critics, but every week, half a million more sign up. Another 20 million people are receiving additional Medicare assistance through employer sponsored drug plans and other coverage options.

Most importantly, these people are saving money. Their monthly premiums have already dropped from the initial estimate of $37 down to an average of $25 per month. CMS reports that the plans they are joining are doing better than anybody expected to increase the use of generic drugs and negotiate deeper discounts with drug manufacturers. This translates into real savings for Medicare beneficiaries, meaning that they are able to reduce their drug spending by thousands of dollars.

We will hear from two Medicare beneficiaries today, including Marcus Hickerson, who is a constituent of mine from Waxahachie, Texas. Marcus and his wife have enrolled in new Medicare prescription drug plans, and will save approximately $2,400 this year.

These savings should not come as a surprise to anyone. Many of us understand that when we give consumers choices, and let free markets and competition work, prices fall. That is what we saw with Medicare prescription drug cards, and that is what we are beginning to see now with the new drug plans.

The critics still don't get it, and some never will. It appears that the Democratic leadership in the House has decided that political advantage may be gained by scaring seniors and discouraging them from enrolling in the new prescription drug plans. They

recently sent out packets of information to all of House Democrats, arguing that patients are not smart enough to understand the new benefit. They say the coverage is spotty at best, and signing up is not worth beneficiaries' time because it cannot possibly save them a dime.

These critics are simply wrong. They were wrong when they complained about the Medicare prescription drug card. They were wrong when they said nobody would offer any insurance plans. They were so very wrong then and they are similarly wrong now.

As I had mentioned earlier, the new benefit and its implementation are hardly perfect. At the same time, I am proud that 81,000 people in my district have been able to take advantage of the new Medicare drug benefit. That's 81,000 people who weren't scared off and who certainly were smart enough to figure it out. Some say my 81,000 constituents have made a big mistake. They seem to believe my constituents should be confused and disgusted instead of pleased. But I'm happy to report that in my district, people are voting with their wallets and their good sense, and they ignoring that bad advice by the tens of thousands.

Now 81,000 is a good number, but we can surely do better. I want every Medicare beneficiary who stands to save anything through this new program to get the information they need and the opportunity to sign up.

I am also going to challenge my Democratic colleagues to join the millions of Americans who expect our priority to be good policy, not good politics. Rather than trying to scare and confuse seniors in the run-up to the November elections, we should work together to do everything we can to get seniors the information they need to make informed choices and to select plans that will save them the most money. At a minimum, we owe that obligation to all Medicare beneficiaries. I promise everyone here that people will appreciate our work, and that good policy will make for good politics.

I want to thank Chairman Deal for calling this hearing, and reiterate my thanks to all the witnesses for coming today. I look forward to their testimony.

MR. DEAL. Thank you. I am going to recognize Mr. Waxman because he wishes to reserve, to waive his opening statement.

MR. WAXMAN. Mr. Chairman, I know Mr. Dingell is going to go next, but I have to go to the Rules Committee, so I won't be here for the opening statement and I just want to ask unanimous consent that my time be added to the question period.

MR. DEAL. Well, under the rules, you would have an extra three minutes. I recognize Mr. Dingell at this time, then, for his opening statement.

MR. DINGELL. Mr. Chairman, I commend you for this hearing and I want to express my thanks to Mr. Barton, the Chairman of the committee, as he leaves us because we are deeply appreciative of his concern for the Democratic members and his invitation to us to participate in the handling of this legislation. I would say that that is quite a new experience for us because this thing, this is a piece of legislation which was conceived in sin, born of the darkness of night with no participation by the Democratic members at all and attended only by a fine gaggle of lobbyists for the healthcare industry, particularly the insurance industry, and for the pharmaceutical industry. No Democrat will claim parentage of this abomination and whether or not

we can save it from the evils that are inherited is beyond my kith, but I am hopeful that the beginning of this hearing will begin to enable us to address the faults in it and to perhaps either take steps to repeal it or in an extraordinary burst of good luck, perhaps to reform it.

Now, having said that, we have sent a letter requesting additional opportunities to be heard and for an additional hearing under Rule 11. I am hopeful that our witnesses today will be able to explain some of the things which are appearing in the papers and I will submit those to them so that they may make a proper comment. I have told many folks that this prescription drug benefit called Part D, the D stands for disaster and most of our senior citizens so view it. While we hear from the Centers for Medicare and Medicaid Services that things are quieting down, that doesn't appear to be the case as we read it in the papers. Simply put, Part D is incredibly complicated with numerous private insurance plan choices, senior haven't got the vaguest idea about how to make the important choice well and that is which plan is going to best serve their purposes.

According to the Kaiser Family Foundation poll conducted in February, 47 percent of the seniors say that they do not have enough information to understand how the benefit will affect them personally. This is not surprising, according to a CMS document, beneficiaries have to go through 17 steps to calculate annual expected drug costs. I would note that by comparison, there are only 12 steps that the IRS has people make in Form 1040 EZ. This shows us that much needs to be done here.

For those who have managed to enroll in a private plan, the concern is whether they are getting what they were promised or if plans are setting up more obstacles and preventing beneficiaries from getting needed drugs. Reports from the field, which come in regularly, indicate that excessive requirements before the plans sign off on whether the drug are covered is required. A myriad of different and confusing mechanisms for filing appeals exist and nobody knows how to appeal, where to appeal or what to do.

There is use of tiered co-pays to charge patients higher prices for drugs that are supposedly covered and these problems are not going to go away. They are part of a vast overhaul that needs to be made on what I regard as an abominable piece of legislation which does discredit to this body, not only in its substance, but in how it was conceived and how it was birthed.

I have introduced legislation which will address some of the problems associated with it and since I have a minute and 17 seconds, I am going to just read, for the benefit of the committee, a few clips which we got from the papers. First, the Washington Post. "Stability of mentally ill shaken by Medicare drug plan problems." And I will ask

that this all be put in the record in good time. Then from Newsday, "Part D spells disaster for many citizens." And this is what the article had to say. A pharmacist for 13 years had this to say. "The whole thing is just mind boggling. Patients are confused. They are ultimately going to get the short end of the stick. They get confused, frustrated and unruly. Most of the problem comes from the dual eligibles."

In Medicare, this from the New York Times today, and I would commend it to the reading of all. It says, "In Medicare maze, some find they are tangled in two drug plans." And it says, "Many Medicare beneficiaries, like Mrs. Beard, tangled in two plans, two hot plans in the lingo of pharmacists. The situation leaves patients at risk of being charged two premiums or incorrect co-payments." It also says, "It is like trying to undo spaghetti." I am sure that the Department of HHS will have some worthwhile comments on their efforts to address this problem.

Last of all, from the Washington Post, again, "Maryland urged to cover funding gaps in Medicare plan." This is something, by the way, which has been an ongoing problem of the greatest dimensions and it goes on to say this, "A lot of very vulnerable people aren't getting their meds, said Herbert S. Cromwell, Executive Director of Community Health Behavioral Health of Maryland, which serves children and adults with mental health problems." This is nothing short of a fiasco. We have a mess on our hands, it is going to get worse. And when people start falling into the donut hole, or as I call it, the black hole, we are going to find out that the popularity of this, which is already very near the floor, is going to go lower. I wish you all success.

MR. DEAL. The Chair recognizes Mr. Norwood for an opening statement.

MR. NORWOOD. Thank you very much, Mr. Chairman, and Dr. McClellan, glad to see you back. I appreciate the strong effort you have been making on this. Mr. Chairman, I would like to welcome my constituent Anne Dennison from Hiawasee, Georgia. We are so glad she is here with us today. She is 72 years young, cancer survivor, and she is actually going to be here to tell us how Part D has helped her, can you imagine? There may be some other people who might have been helped by Part D, too. Anne, we are so happy you are here. I am not going to mislead anybody. I have concerns about this benefit and Congress will need to take a long look at it in the future, but isn't that true of all of Medicare as a whole?

However, Part D is the law and it is actually working. Did it work perfectly on day one? Heck, no. It surely did not. Do I believe that some problems could have been prevented? Yes, they could have. I think so. However, I also think that this benefit will continue to get better and I have lots of in-the-field reasons to believe that to be true. In

truth, many of the problems that were encountered in January were the result of miscommunication or no communication between CMS and the insurance plans and the pharmacies regarding dual eligibles. That is where the basic problem was. These problems have largely, though I am sure not completely, been worked out.

We need to make sure that every dual eligible is getting the medications that they need at the appropriate price. We need to make sure that everyone who overpaid gets repaid, refunded. Now, this was the government's error and I don't trust the insurance plans to make sure that wrongful payments are returned. That just comes from a long history of mistrust. I have talked to pharmacists in my district and the money they put out to make this program work proves that they have been the frontline warriors for this plan. They are owed our praise and thanks, but more importantly, they need their investment back. But the program is working, premiums are falling, and purchases of medication abroad which are inherently unsafe have plummeted.

However, it is not all sunshine yet and we will be keeping a very close eye on these Part D plans, as I am confident Dr. McClellan will, too. And I don't say that very often about CMS. I say to all insurance plans, if you think you will alter your formularies to avoid high-cost drugs, that you will use prior authorizations on every refill to discourage usage, conclude to drive community pharmacists out or undermine the competition of the market, this committee is going to be watching. Since we don't have solid patient protections in these plans, I expect CMS to work with this committee to be the gatekeeper that seniors deserve and I believe we are going to need. Mr. Chairman, I truly thank you for calling this important hearing and I will look forward to the testimony of all of our witnesses.

MR. DEAL. Thank you. Ms. DeGette is next for an opening statement.

MS. DEGETTE. Thank you very much, Mr. Chairman. I will waive my opening statement in favor of extra time for questioning.

MR. DEAL. Ms. Capps is recognized.

MS. CAPPS. Thank you, Mr. Chairman, for holding these hearings. These hearings can't come soon enough. Since implementation of Part D prescription program began, I have been hearing pleas for help from my constituents, including beneficiaries, pharmacists, and State and county public health officials. Because the Administration seems to be tone deaf in its praise of this program, I think it might be helpful to give you a couple of real life stories from my district, because you can't simply brush off what has happened as minor glitches in the system.

Every day so many real people are suffering. They can't access their necessary medications and they are dealing with the problems that this

creates. Take, for example, the many mentally disabled patients who are duly eligible. Many of them can't figure out what the different premiums in co-pays would mean for them. They never could figure that out. I have heard from my district staff about certain patients who simply never check their mailboxes. Perhaps they have a diagnosis of paranoid schizophrenia and therefore, they will never know about the changes in the system or what new plan they have been assigned to. When they arrive at the pharmacies, the pharmacist can't figure out what plans these individuals have been arbitrarily assigned to, either, and it can take several visits and hours. We have documented many times this happened, hours of waiting on the phone to speak with representatives from Medicare and/or the insurance plans, all the while these people are going without essential medications that protect against dangerous behavior to themselves or to others.

I have heard from the Santa Barbara County Public Health Department about a patient who had difficulty getting medication for his diabetes. The patient actually did know which plan he was assigned to, but neither he nor his pharmacist could figure out which tier he was in. By the time he went to the doctor, he had gone two weeks without medication and had a blood sugar level of 560. The health department also informed me about an HIV patient who needed a medication that had always been covered under MediCal, that is Medicaid in California. His plan, however, would not approve the necessary dosage prescribed by his doctor. He therefore had to go to the emergency room four times a week to receive his medication. He could not afford to pay for it out of pocket, but it was so crucial that he receive this life saving medicine. Where is the logic in this?

How can we simply tell people that the kinks will be worked out and that they should just be patient? We have a responsibility to ensure that our seniors and disabled receive prompt and affordable coverage for their prescriptions. Instead, beneficiaries on fixed incomes are being forced to pay co-pays for the very first time ever. While a $3 co-payment may not sound like much to the people in this room, imagine what it means for someone living on $800 a month and taking ten medications. Medicare is supposed to be a lifeline. It provides life saving help and unfortunately, this new drug plan has failed that test. I look forward to hearing your explanations and solutions and I close with a statement from a letter that I just received this last week from a senior, and this is her statement to me. "This is a good way to get rid of the old and the poor."

MR. DEAL. Mr. Shimkus is recognized for an opening statement.

MR. SHIMKUS. Thank you, Mr. Chairman. Well, I have a few letters, myself. An e-mail from John Barker, who e-mails us, says, "I

just called to say that the prescription drug plan I helped my mother choose is great and has drastically reduced her costs." I got a letter from Genevieve Hepke--Mr. Barker is from Hamilton County in Illinois, one of my most rural parts of my district. I represent 30 counties. And now a letter from a St. Louis suburban area, from Genevieve Hepke from Edwardsville, Illinois, "Just a note to thank you for the informational meeting on the Medicare prescription drug plan given at the Edwardsville YMCA today. I have spoken with several representatives from insurance companies recently and still had only a vague idea of how to proceed with choosing a plan. The SHIP counselor," which is a Senior Health Insurance Program individuals, and I want to applaud them. They have just been wonderful helping our seniors. "The SHIP counselor who explained the program today walked us through from start to finish with a pleasant presentation and all the information we could possible need. She was very good. Again, thank you for offering this program and also the wonderful work you are doing in Washington. You make us proud. Sincerely, Genevieve Hepke."

And I also want to recognize the local Area Agencies on Aging who has helped me through probably 12 or 15 Medicare D forums that I have held. Usually I welcome the seniors. They have all been well attended, probably anywhere from 60 to 100 seniors at each event. I usually welcome them, kind of give them the intent of why we passed the legislation, which is to make sure that poor seniors have access to prescription drugs. And then I turn it over to more experts than me, which is usually the folks from the local Area Agencies on Aging or the SHIP counselors, who, as these letters highlight, have just done a tremendous job and Mr. Chairman, I just want to take this time to recognize those folks. We have had, you know, problems and challenges like everyone else.

I also want to take the remaining 40 seconds that I have to also thank the local pharmacists. They have struggled and we all know that. But you know what? Especially in small town rural America, they know their customers and their concern for them and they have done the yeoman's work and the success of this program really can be tied directly to the local pharmacist's counter in their local stores, and so with that, Mr. Chairman, I want to thank you. I think the program is going to continue to be a great success for our seniors in America and I yield back my time.

MR. DEAL. Gentleman yields back. Mr. Davis is recognized for an opening statement.

MR. DAVIS. Thank you, Mr. Chairman. I thank you for being here today, Mr. McClellan. I did not vote for this bill, but the purpose of this hearing today is to decide how to make this work. I want to say that in

my nine years of Congress I have never heard as much outrage expressed as I have about the prohibition in this bill against the Federal government negotiating discounts just as Costco, the Veterans' Department, or the Department of Defense would for lower prices on pharmaceuticals to protect the taxpayer and the Medicare beneficiaries and that is certainly something that should be addressed here and hopefully in future hearings.

Perhaps one of the few things that can be agreed upon here today by you and the Democrats, Republicans are that some people are benefiting from this, but not enough, and my State, Florida, is one of 27 States that has had to cover the cost of the dual eligibles to prevent the type of people like Representative Capps referred to from slipping through the cracks. My Governor did so only because through March 8 you have extended the authority of the Federal government to hold the States harmless so one of the questions I would like to ask you today and I will be submitting written questions to the record is what are your intentions as far as extending that deadline beyond March 8 and will you continue to reimburse States if the problems that existed before March 8 are not taken care of?

I also can report to you, and I hope you have heard this, as well, there are many independent community pharmacists who have difficulty making ends meet that are having to absorb a lot of these costs themselves and they are running out of the ability to do so. In Carrabelle, Florida there is one pharmacy who has told us that they are about to stop handling the Part D benefit entirely unless somebody steps in to make sure that these HMO plans are covering the expenses as they are supposed to. One of the questions I would like to ask you is whether you use the authority this Congress gave you to sanction any insurance plans that are failing to reasonably and timely reimburse these pharmacies who are at risk of not continuing to provide the benefit.

I also would like to ask you to address why you are not willing to support extending the enrollment period beyond May to avoid the penalty that many of our constituents are going to have to pay because I think it is fair to say there are still millions of seniors out there who cannot navigate through this maze of plans. Many people here in Washington have claimed responsibility for that, but why don't we claim some further responsibility and extend the enrollment period past May and not punish the senior who are not responsible for these problems that were created? So I hope you will be open and you will be honest about what is happening out there. There are numerous problems and it is our obligation to address them and there are many lives in the lurch here and many people's health is at stake in how we deal with these problems. Thank you, Mr. Chairman.

MR. DEAL. Mr. Buyer is recognized for an opening statement.

MR. BUYER. I tried to pay attention to some of the words that I have heard here and I suppose I have to put it in context. So isn't it just an abomination that millions of Americans have access to drugs that they have never had access to before? An abomination. It is just awful that people have access to drugs, isn't it? It is just awful that seniors have a choice in selecting plans that can best be tailored to their physical characteristics and needs. Choices must be awful in a free society.

Dead horse. The only dead horse I see are advocates of a command economy. If you want to live in America in a free society and you believe in liberty, then you believe in a demand economy. You believe in the marketplace of ideas that give us the greatest drugs and blockbuster drugs in the world. The quest is for the access of those drugs. So these ideas that are thrown out there, oh, Steve, let us just have the VA do the pricing as if what, that hadn't been tried before? In 1990 when Democrats controlled Congress, they said you know, that is exactly what we are going to do. Those 3.5 million veterans out there that have access to it, you know, even though they only take 1 percent of the drugs, yeah, let us give them access to those price controls. Whoa, really.

So we take 41 million Americans, those 41 million Americans make up 40 percent of the available drugs and you don't think there is going to be a cost shift out there? When that occurred, there was such panic, about a thousand percent increase in prices to the veterans, that immediately Democrats overturned what they had done. So if you want to keep talking about that, please do a little look back on history on what Democrat leaders did and their failure and actually their recognition of their failure. That was a dead horse.

So if you want to continue to talk about these things, the horse, which I think is being ridden on the other side, is a unicorn because it is pure fantasy to believe that if you are going to have price controls in America, that we are going to be the land that will create these blockbuster drugs that will provide a quality of life to people, not only here but throughout the world.

Now, Dr. McClellan, you sent a national letter out there and CMS did requesting a 90-day look back on electronic reconciliation. I want you to know that these co-pays and deductibles and dual eligibles are still a concern. Did a quick test on three different sized pharmacies in Indiana and they are still running about 10 percent. You use the word requested, I would love to see the word required and I will join with my colleague with regard about questions on your authority.

I also concur with my colleagues about the pharmacists being real heroes out there. They are in a pinch, and right now, what I would call it is, what is required is economic defibulation because--I just made it up.

Economic defibulation is their payment schedules are completely out of whack. They were all used to particular payments from Medicaid and so what, wholesalers knew when to be paid, manufacturers knew when to be paid, suppliers knew when to be paid, but right now it is all different. It has been changed. So I would like for you to work with us. We want to bring in manufacturers and wholesalers to get it right and the predicate to do this are the plans because we are going to pay into the plans, the contracts are in place, enforceable contracts, and then we can get everybody back on a proper payment schedule. That is what I call economic defibulation. I yield back.

MR. DEAL. Ms. Baldwin is recognized for an opening statement.

MS. BALDWIN. Thank you, Mr. Chairman. Dr. McClellan and welcome to the very patient witnesses for our second panel later today. Many of the concerns that led me to vote against the legislation that created this drug plan are being born out, but as I cast my no vote at 3:00 a.m. and then waited three more hours during arm twisting as the majority rounded up the votes they needed to pass this, I really at that point could never have imagined or predicted the conversations that I would be having with my constituents since the rollout of this program began.

It started when thousands of Wisconsin's seniors received their 2006 Medicare and You handbook, which included substantive mistakes, specifically regarding the low-income subsidy, but we were unable to persuade the Department to send out any sort of errata communication. Then, over 2,000 Wisconsin seniors were auto-enrolled in plans by mistake and then, as I met with constituents, seniors, senior advocates, and pharmacists were confused, as we have heard, overwhelmed and frustrated.

I happened to be holding listening sessions throughout my district last year as the rollout was occurring and wherever I went, I was sure to get several questions; what were you guys thinking when you came up with this plan? Why did you make it so complicated and why can't it be like the rest of Medicare? But these were the mild responses. It was not uncommon for me to spend time one on one with a senior who had just burst into tears as they explained their experiences with the program and their anxiety about whether they would find a way to remain on a life-saving drug.

However, I knew it was really bad when at one of my listening sessions, I met with the staff of that county's office on aging who had come over to the listening session location after work to let me know about their concerns and one of the workers even burst into tears as she was describing all of the impediments that she had encountered as an advocate for dual eligible seniors in her county. I know we are here to

talk about the implementation of Medicare Part D today and how we can do better, but I think it is also important to note that there are a number of issues that cannot be fixed administratively because they are built into the law that created Part D.

I still believe that the government should be able to bargain for lower prices, that plans should not be able to change their formularies more frequently than beneficiaries are able to change their plans and that beneficiaries who are misled or misinformed should have recourse and that we must extend enrollment penalty deadline beyond May 15th. Thank you again, Mr. Chairman. I yield back.

MR. DEAL. Dr. Burgess is recognized for an opening statement. This is the notice, I think, for the votes at 3:00. No, the vote is at three o'clock. There will be one vote depending on how we are in terms of opening statements and getting started. It may be that it comes at the point before your testimony, so we will go ahead if you will proceed with your opening statement.

MR. BURGESS. Thank you, Mr. Chairman. I have an opening statement that I will submit for the record, but I have a couple of other observations. First, I do want to welcome my constituent, Mr. Dennis Song, to our second panel today. Dennis has been a longtime friend. He is a pharmacist back in the district and does a great job running an independent pharmacy. Dennis ran the first 24-hour pharmacy when I started in practice in Louisville, Texas, and we had many occasions to talk about things late at night.

And not wishing to just unsolicitously pander to the pharmacists, I will tell you, Mr. Chairman, that I have heard from a number of pharmacists in my district, as well, and the pharmacist, Bill New in Denton, was very kind and would always call me up and say I am going to put you on hold with the hold music that I am getting from the drug plan so you will be able to listen to it with me and that was very kind of him. They played some rather catchy tunes. But I do think that the problem has ameliorated over the past several years, but Dr. McClellan, you know my frustration and my anxiety for pharmacists in the district and throughout the country that make good on the patients' needs and sent them out of the pharmacy with the prescriptions which Secretary Leavitt told them to do. I think we need to go one step further and assure the pharmacists that we would do everything we could to make certain that they weren't carrying the entire freight for that.

With the benefit of hindsight, yes, perhaps it wasn't the best idea to bring the dual eligibles in at the very first of this program. We can't undo the past, but certainly they can make the argument that we are having this hearing a month late and perhaps we are, but the reality is the prescription drug benefit is 40 years late and seniors who signed up for

Medicare those first days back in 1965 when they were 65 years of age are now 106 years of age waiting for that prescription drug benefit, so I hope it doesn't take us that long to get this right and I don't believe that it will. And I do believe that fundamentally it is a good plan.

As part of my research in getting ready for this hearing, looking back over what was proposed in the previous Administration in the year 2000, March 9 of 2000, in fact, when the President and Senate Democrats were unified, there was a press release from the White House, the President and Senate Democrats are unified in a vision for the Medicare prescription drug benefit and amongst the principles that they have enumerated here, that it would have to be voluntary; I believe ours is. It would have to be affordable for beneficiaries of the program. Here is an interesting one. It has to be administered using private-sector entities and competitive purchasing techniques.

They go on to say discounts should be achieved through competition, not regulation or price control. Well, that is probably a pretty good idea and for once I find myself in agreement with the Clinton Administration. Mr. Chairman, Chairman Barton of the full committee said we are going to have aggressive oversight of this program, so I certainly thank you for holding this hearing today. I am going to take Chairman Barton at his word. I hope that this is the first of several visits that Dr. McClellan will have here. We will name that the "McClellan Chair" in the Energy and Commerce Committee. It is going to require a lot of work on the part of this committee to make certain this is done right, but we owe nothing less to the American people. I yield back.

MR. DEAL. Mr. Pallone is recognized for an opening statement.

MR. PALLONE. Thank you, Mr. Chairman. I am amazed by my colleagues on the other side attempt to rewrite history is, I guess, the best I can say. I think the gentleman from Texas should remember that the Democrats, to the person, I think, every Democrat, voted for a Democratic substitute to this legislation that would have been very much like Part B, under Medicare, not privatization, very simple, $25 a month premium, $100 deductible, 80 percent paid for by the Federal government, 20 percent co-pay, all drugs included, go to any pharmacy, all the choice you want and negotiated price reductions, just like the VA and the military, so when you say what was the Democratic alternative, we had a Democratic alternative. It was a good alternative and it was one that would have avoided all the mass confusion that we are living with now under this Republican bill.

The other thing I wanted to comment, but the comments that the gentleman from Indiana made, I think that his problem is that he is looking at this strictly from an ideological point of view. I don't think he is here now, but I have to comment. He talked about command and

control. Do you think that when I have my town meeting in Edison that my senior citizens--I had a town meeting in Edison last week, we had about 150 seniors--do you think that they care about command or control or that they see, you know, Medicare Big Brother swooping down on them and telling them what to do with their drugs? I mean, they are not looking at it that way. They are just looking to survive. You know, he talked about choice. They don't think they have any choice because now they are being limited in what drugs they can choose, what pharmacy they can go to. That is not choice.

I mean, the first thing that I was told by the seniors at my forum, they wanted to know why there were not negotiated prices, why the government wasn't doing what we do with the VA and the military to keep the prices down and I had to say look, the only reason I can think of is because this bill was written by the pharmaceutical and the insurance industry and it wasn't written for you because the President wasn't concerned about how this was going to work out for you. I want to be honest with you. All I get from my seniors is mass confusion. They just want a simple program, they are very comfortable with Medicare, you know, the way it is traditionally. They would have been very happy if we just expanded the Medicare program to include a prescription drug benefit and I want, in the time I have left, I just want to commend Mr. Dingell for this letter that he wrote asking for more oversight because I think it is absolutely necessary.

Several of the Republicans talked about the problems at the pharmacies. I went to a pharmacy in my district last week or two weeks ago and again, mass confusion. Pharmacists are shelling out all kinds of their own money because they don't want to turn people away. We need an oversight hearing on the pharmacy issue, we need an oversight hearing on the States and how they are going to be reimbursed and what they are going to do. I mean, I do appreciate the fact that some of my Republican colleagues said that we are going to take our oversight responsibility seriously and that should be to respond to our letter and have several more hearings on various aspects of this because I am not going to call it names. It is just mass confusion. That is what it is. It is very simple. And anybody who tells me that there is not tremendous confusion out there, I think is just kidding themselves. Thank you, Mr. Chairman.

MR. DEAL. Mr. Pitts is recognized for an opening statement.

MR. PITTS. Thank you, Mr. Chairman. I will submit my opening statement for the record.

[The prepared statement of Hon. Joseph R. Pitts follows:]

PREPARED STATEMENT OF THE HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF PENNSYLVANIA

- Chairman Deal, I would like to thank you for convening this hearing today on such an important issue.
- In my district in Pennsylvania, there are 101,576 Medicare beneficiaries eligible to enroll in Medicare Part D. As of February 11, 46,481, or 46%, of them have chosen to do so.
- According to CMS, only 65% of those eligible in my district are expected to enroll in Part D this year. Yet, the average expected enrollment across all of Pennsylvania is 72.5%. The estimated 2006 enrollment for the districts of three Members of my delegation is 95% or higher.
- I am concerned with the 35% of Medicare beneficiaries in the 16th district who are not expected to enroll in the program, and it is my hope that our witnesses today will shed some light on why so many of our seniors are choosing not to participate and how we can encourage them to do so.
- Those already enrolled in Part D and the pharmacists who serve them have faced difficulties and confusion in the opening days of the program –
    - seniors who did not know that they had already been enrolled in plans,
    - dual eligibles hit with co-payments larger than they expected,
    - pharmacists dispensing drugs without knowing if the plans or the state would reimburse them.
- I am pleased that many of these problems have been resolved; however, the program still faces many more, which we will address today.
- Mr. Chairman, I welcome the opportunity today to hear testimony from Dr. McClellan and the rest of the witnesses.
- I yield back my time.

MR. DEAL. Mr. Bilirakis.

MR. BILIRAKIS. Thank you, Mr. Chairman. Yes, we should have more oversight and yes, we should have more hearings, but I should think when we have those hearings, just as the hearing today should be, we should be open minded; we should be here to realize that we are trying to learn. This is an educational process. But when we come into a hearing, Mr. Chairman, as some have and they refer to certain newspapers and whatnot, and that is their means of education, that is the way that they see the program, I just wonder how open minded we really are.

There is a recent issue of the AARP magazine with multiple pages on the plan. It just lays it out with illustrations and whatnot. It does a very good job and it encourages the seniors to not just randomly basically not take the plan and not consider the plan, but take into consideration many things, such as particularly the catastrophic portion of it all because you may not have much of an illness today and you don't have much of a need for drugs today, but no one knows what the future holds. That should be, that is part of education, too. But if we were going to be depending on what we read in the newspapers, I am here to tell you that Medicare would have never gotten off the ground.

Take a look at those same newspapers back in the mid-60s and what they said about Medicare, about all the complexities, and all the problems that people were having. People were not signing up for it and that sort of thing and if we had taken all that, not we, but those who were here at that time, if they had basically said we are going to discard it because the newspapers say hey, there are an awful lot of problems and it is no good, then we would not have Medicare today. So Mr. Chairman, we are just not open minded, and we talk about wanting to have hearings, well, it is just another opportunity to get up here in a very partisan and biased manner, just express our point of view, not on a basis of education, and what we are really learning.

I spent some time in a pharmacy in my district last week and I went into the back where the pharmacists are and I talked with them and I listened when they talked to patients, so I went up with them and talked to the patients and that sort of thing and you know, it is not perfect. I didn't hear a single patient who complained about the plan on that particular day. I am sure I could pick another day and there would be a patient or two who might complain about the plan or may have questions that possibly the pharmacist cannot answer, but that is the way, I think, that we learn. That is the way we learn. I don't think we learn just by picking up the newspapers or coming up here, shutting our ears to any of the testimony.

We have pharmacists here today. We have patients here today and hopefully we will open up our ears and listen to them. And there are problems and people have expressed some of those problems. There is no question about it and we are going to have to do some molding and remolding as time goes on, but this is basically what we have done with Medicare, too, and so hopefully, Mr. Chairman, we can all work together if we really want to, rather than continue to throw stones at each other and I think we are going to have a plan that we will be proud of in the future. Thank you, Mr. Chairman.

MR. DEAL. Thank the gentleman. We are getting close to the time the vote is going to take place. We are going to continue with opening statements and we will rotate someone in the chair so that we can hopefully get through these during this vote. It is only one vote. So if you have made your opening statement, you may want to leave and go vote early and come back. We are going to be rotating. Mr. Strickland, you are next.

MR. STRICKLAND. Thank you, Mr. Chairman, and I will be very brief. I have listened to the comments of my colleagues on both sides of the aisle. I think Mr. Pallone was absolutely correct. Seniors are confused, many of them are frightened. They don't know what to do. Pharmacists are upset. We are listening to our constituents, that is who

we are listening to. We are listening to the people in our districts and the newspapers, I think, are reflecting what they are hearing from the citizens across this country. I think the greatest example of the utter failure of this plan is the fact that when the President of the United States gave his State of the Union Address, this which was supposed to be one of the two or three most valued accomplishments of his presidency so far was not mentioned, not one word, and the reason it wasn't mentioned is that he knows, and we all know, that this is a deeply flawed, perhaps fatally flawed program. It is going to have to be changed dramatically.

I would like to see it repealed and we start all over and do what we should have done and that is add a benefit that is a part of Medicare, that is a part of Medicare easily understood, easily financed, that does provide choice to our seniors. Our seniors have lost choice with this plan and they are angry and that is why the President of the United States, giving his State of the Union Address failed to even mention that this body had passed this, what was supposed to be a very successful, meaningful domestic policy. So with those comments, I look forward to the testimony that is going to be given to us today and I yield back the remainder of my time.

MR. DEAL. Thank you. Mr. Pickering is recognized for an opening statement.

MR. PICKERING. Mr. Chairman, thank you very much for having this hearing. To Dr. McClellan, I want to thank you for your leadership. I know that this is not the easiest time between dealing with irritable Members from the Katrina region and trying to implement a major, major change in Medicare Part D. We appreciate your commitment to solving the problems and making things work and correcting things as they are brought to your attention. I look forward to your testimony and I look forward to working together with you, whether it is from our region or for those who are now eligible for Medicare Part D, to get the best plan for them at the best price. So thank you for your leadership.

MR. DEAL. Thank the gentleman. Mr. Rush.

MR. RUSH. Thank you, Mr. Chairman, and I appreciate you holding this hearing, also. And I also want to welcome Dr. McClellan again. Mr. Chairman, it has been demonstrated in this hearing so far, there are vast differences of opinion regarding both the enrollment and the effectiveness of the Medicare Part D program that was enacted into law. Mr. Chairman, two weeks ago we sat in this same room and we heard the Secretary of Health and Human Services, Michael Leavitt, tell the full committee that our seniors were becoming excited about the new Part D benefit and that they were starting to enroll in the new program in increasing numbers.

The Secretary's contention was that seniors were really starting to understand how the new system worked, that they were beginning to enthusiastically support the new program. As the Secretary was making these comments, I was astounded. I thought to myself who is he talking about? Who are these seniors? Who are these beneficiaries and where are they? Certainly, the experience in my district does not bear out his comments; it is vastly different in my district. Mr. Chairman, I am telling you and other members of the committee that my seniors are completely confused, they are frustrated, they are confounded and they are fighting mad with this new Medicare Part D benefit program.

Mr. Chairman, the numbers that the Secretary espoused bear the fact out that this is a confused state that our seniors find themselves in. Only 4.9 million seniors who are eligible have actually signed up for this Medicare Part D drug coverage. Just last week I held yet another seminar in my district on the south side of Chicago to help my constituents navigate the complicated maze of private insurance carriers and their various benefit packages, the second one, and we plan to conduct more. I found that my constituents are completely confused. They do not understand the basic elements of the new program.

I am particularly worried about the senior citizens and those seniors who may be immobile or who have lost some of their mental capacity. Who is helping these folks? We need to do a better job and as such, Mr. Chairman, I am pleased that we are having this hearing. I want to close by suggesting that members of this committee seriously consider legislation that would extend the May 15 deadline for enrolling in the program and make other reforms that simplify the new benefit program. We are not meeting our goals. We are not meeting our objectives. We are really not meeting the interests of the American people, particularly the elderly and those who depend on Medicare for their basic healthcare coverage. With that, Mr. Chairman, I yield back the balance of my time.

MR. DEAL. Mr. Hall is recognized for an opening statement.

MR. HALL. Mr. Chairman, would it be too much if I asked for a second reading of all the speeches that have been made here?

MR. DEAL. It would be too much.

MR. HALL. I will yield my time back and I will ask unanimous consent to put a statement in the record.

MR. DEAL. Without objection. Ms. Eshoo.

MS. ESHOO. Thank you, Mr. Chairman, for having this hearing and I hope that there will be a commitment of the leadership of the committee to hold more in terms of oversight because I think it is a must. It is good to see you, Mark. I don't know how glad you are to be here, but I have a printed statement for the record and I just want to say the following. I have the privilege of representing an incredibly distinguished

Congressional district, you know that. You were a part of it at one time and I think there are more Ph.D.s in my Congressional district than any other place in the country, so people are very sophisticated. They don't really identify with a solid Democratic answer or a solid Republican answer. You give them the information; they will make up their own minds.

Their report back to me is that this is a real Rube Goldberg plan. I didn't think that it was sound public policy when it was presented, but I weighed in. I didn't vote for it. What we are doing here today is really reacting to what the reception in the country has been of the plan now that it is the public policy of the United States of America. So we are going to have to, I think, first of all, to be honest about it and what the problems are. It is confusing, it is enormously complex. Pharmacists in my area, Mark, are not happy. They are pulling money out of their own pockets to help people. The whole issue of the card that people got to begin with, I think should have been instructive to CMS because what problems were experienced then have now been passed over to the system, so I am going to direct my questions to you about what you plan to do to fix some of these things.

I think some things are not repairable because the legislation, I think, represents flawed public policy, but there are some things that we can do and I want to know, in my questions, what you support, what you don't and of course, I will listen to your testimony, as well. I think this could have been done much better. I think it could have been much clearer. I think it could have been far less complex and I might say if it was less ideological we might not be experiencing the problems that we are now, so but as I say to my constituents, I will do everything I can to try and fix and repair something that you are having to live with. They are not happy, they are not pleased and I think that this has given choice a really bad name and that is what my constituents say and as you know, Mark, they are quite sophisticated. So I am going to go and vote and then come back and ask you some questions. Thank you, Mr. Chairman.

MR. DEAL. Mr. Allen.

MR. ALLEN. Thank you, Mr. Chairman. I appreciate your calling this particular hearing to examine the current status of the Medicare Part D program. Speaking for my constituents in Maine, I have to say that the process has been chaotic. The Medicare Modernization Act of 2003 gave the pharmaceutical industry and the insurance industry most of what they wanted, but it denied senior citizens and people with disabilities the simple option of adding a Medicare administered prescription drug plan to their Medicare benefits. Instead, this law forces beneficiaries to sort through the ever changing array of plans, premiums,

co-payments and formularies offered by dozens of private insurance companies in each State.

Because Medicare is prohibited from negotiating price discounts, the drug benefit will never provide beneficiaries with a reliable and affordable access to prescription drugs. The gentleman from Indiana was talking about the problem of having price controls in America. Well, what we are talking about is good enough for the VA, it is good enough for Medicaid, it is good enough for military retirees. If those are price controls, I would say people under Medicare should have the benefit of them.

Maine is fortunate that we had a Governor that was committed to ensuring access to prescription drug coverage to all Medicare beneficiaries and that meant assuming a very hefty financial burden without a guarantee of full Federal reimbursement. We had such chaos in this transition period. Maine has now spent $6 million of its own money to ensure that low-income beneficiaries have access to the prescription drugs because the plans weren't working, CMS wasn't coming through the way we needed it.

I want to say that a lot of this has to do with the dual eligibles and back in March or April of last year, Senator Rockefeller and I introduced legislation that would have extended the period for the transition for dual eligibles from essentially six to 10 or 12 weeks, whatever it was, to six months and we were assured over and over again by CMS that it is no problem, it is going well, we won't have an issue here.

I do want to welcome Jude Walsh today. She is the director of pharmacy assistance in Maine. She is here to share her thoughts on managing the Part D program from the States' perspective, particularly this challenge of handling the dual eligibles, moving them from Medicaid to new private plans. And then lastly, I would just say this, no amount of public relations spin can cover up the frustration Americans have experienced during the two months of implementation of Medicare Part D and I agree with Mr. Strickland. If this plan is so good, the President, when he had a national television audience during the State of the Union speech, would have mentioned it at least once. We need a better plan, we can work toward a better plan and I do think this hearing is a start toward gathering the information we need and with that, Mr. Chairman, I yield back.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF THE HON. ED. TOWNS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

WHILE I UNDERSTAND THAT THE CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) HAVE BEEN WORKING DILIGENTLY, THE

MEDICARE PART D PRESCRIPTION DRUG BENEFIT PROGRAM HAS BEEN PLAGUED WITH PROBLEMS AT EVERY LEVEL SINCE ITS IMPLEMENTATION.

SINCE THE PROGRAM WENT INTO EFFECT, CONGRESSIONAL OFFICES HAVE BEEN FLOODED WITH CALLS ABOUT THE PROBLEMS THAT BENEFICIARIES ARE HAVING ACCESSING VITAL MEDICATIONS.

FIRST OF ALL, MANY BENEFICIARIES ARE CONFUSED ABOUT WHETHER OR NOT THEY SHOULD ENROLL IN PART D. ADDITIONALLY, MANY ARE FRUSTRATED BY THE CHOICES OF PLANS AND CONFUSED ABOUT PICKING THE PLAN MOST SUITED TO THEIR NEEDS.

YET THE PROBLEMS HAVE NOT STOPPED THERE. MEDICARE BENEFICIARIES WHO THOUGHT THEY WERE ENROLLED IN PART D PLANS ROUNTINELY ARRIVE AT PHARMACIES TO DISCOVER NO RECORD OF THEIR PLANS. LOW-INCOME MEDICARE BENEFICIARIES ARE BEING ASKED TO PAY HUNDREDS OF DOLLARS FOR THEIR MEDICATIONS BECAUSE THEIR PART D INSURANCE PLANS HAVE NOT BEEN UPDATED WHEN ENROLLEES QUALIFY FOR LOW-INCOME SUBSIDIES.

DUAL-ELIGIBLE BENEFICIARIES ARE DENIED COVERAGE FOR NECESSARY MEDICATIONS WHEN THE PLAN, INTO WHICH THEY HAVE BEEN AUTOMATICALLY ENROLLED, DOESN'T INCLUDE THEIR MEDICATION ON ITS FORMULARY. THIS IS REGARDLESS OF THE FACT THAT CMS HAS ASKED ALL PLANS TO PROVIDE A 30-DAY SUPPLY OF NON-FORMULARY DRUGS TO NEW ENROLLEES.

PHARMACISTS ARE BEING FORCED TO SPEND HOURS ON HOLD WITH MEDICARE AND PRESCRIPTION DRUG INSURANCE PLANS SIMPLY TO VERIFY BENEFICIARY ELIGIBILITY.

CLEARLY THE DISCONTINUITY OF HEALTH SERVICES EXPERIENCED BY MEDICARE BENEFICIARIES IS INEXCUSABLE. UNFORTUNATELY, THE PROGRAM STILL IS NOT MEASURING UP AND BENEFICIARIES IN MY DISTRICT AND THROUGHOUT THE NATION ARE BEING NEGATIVELY IMPACTED. AS MEMBERS OF CONGRESS, WE ARE ENTRUSTED WITH THE RESPONSIBILITY OF PROTECTING THE NATION'S HEALTH. IT IS IMPERATIVE THAT CONGRESS MAKES IT CLEAR TO AFFECTED PARTIES AND BENEFICIARY GROUPS THAT WE ARE AWARE OF THE PROBLEMS WITH THE RECENTLY IMPLEMENTED PROGRAM AND DO NOT VIEW PART D AS A SUCCESS.

ADDITIONALLY, I CHARGE CONGRESS TO CONTINUE TO HOLD THE CENTERS FOR MEDICARE & MEDICAID SERVICES ACCOUNTABLE AND FORCE CMS TO MAKE THE NECESSARY CHANGES TO ENSURE THAT BENEFICIARIES ARE ABLE TO ACCESS LIFE-SUSTAINING MEDICATIONS. THANK YOU MR. CHAIRMAN.

PREPARED STATEMENT OF THE HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

The implementation of the Medicare prescription drug program has been difficult and disappointing. It has been filled with confusion and disruption. It has caused anxiety and serious problems for people trying to get their medicines.

January 1 should have been a red letter day for America's seniors and persons with disabilities. That should have been the day when they finally got simple and dependable coverage of their prescription drugs as a regular part of Medicare. Their Medicare card should have been enough to give them access to their drugs in any pharmacy in America.

Instead, the benefit came in the form of coverage through hundreds of private plans, each different in coverage and conditions, each different in cost and the price of drugs

covered. The choices were dizzying and difficult. People spent hours trying to decipher the variables in the plans, made a choice, and then found the information changed the next time they looked.

And that was just the beginning. When people tried to go in and get their drugs, they found their eligibility couldn't be established, or their drugs weren't covered. The people who had been covered under Medicaid and who were switched summarily on January 1 were the worst off. But they weren't the only ones with problems.

All of these difficulties in implementation were the result of a combination of problems: a flawed design for the benefit, a failure to anticipate implementation problems, and too big a job for too little staff.

Certainly, there are people who weren't covered before who are pleased to have the new benefit. We will hear from some today. And certainly we all welcome success stories, and we want this benefit to work. But the fact is, for too many seniors and persons with disabilities, it has not worked; it has been a disaster. This is clearly unacceptable. Trying to gloss over the situation by claiming all is well, as this Administration seems to want to do, is a disservice to all those people who continue to have serious problems getting coverage.

Further, I fear this is just the beginning. We know plans can change their formularies after people have enrolled. We know they can raise their prices—that has already occurred. That affects what people pay in coinsurance and in the period when there is a gap in coverage—the so-called donut hole. Again, for people who picked their plans because of the coverage of a certain drug or its price, to pull the rug out from under them and change things is just plain wrong.

We know that the success in enrolling subsidy-eligible low-income people has been abysmal. We all know they are the most certain to benefit from this program, and yet we are not reaching them. One major reason for this is the complications caused by the assets test. We should fix that. Yet we have no proposal to do this from the Administration.

We know that with all this confusion and problems, it is folly to hold a threat over seniors in the form of a financial penalty if they don't enroll by May 15. And yet the Administration refuses to support such a legislative change.

In the end, we need the option of a simple Medicare benefit. That should be the first choice available to all beneficiaries. It should work like other Medicare benefits. It should be the beneficiary's choice if they want to select an alternative to traditional Medicare. And we should use the purchasing power of Medicare's beneficiaries to get better prices from the drug companies.

This should not be about protecting drug company and insurance company profits, but about getting the best price and the best coverage for America's seniors.

MR. BILIRAKIS. [Presiding] Well, we don't know how many will be returning so that being the case, I hate to be the only one listening to your testimony. I am going to wait about maybe two minutes, if I may, with your indulgence.

[Recess]

MR. BILIRAKIS. Into our seats, please. From here we spend a lot of time together these days, actually over the years. Going all the way back to the days when we were the minority, I believe. Dr. McClellan makes up the first panel. He is the Administrator, as we know, of CMS. Sir, you have 10 minutes. Please proceed.

STATEMENT OF HON. MARK MCCLELLAN, ADMINISTRATOR, CENTERS FOR MEDICARE & MEDICAID SERVICES

DR. MCCLELLAN. Okay. Thank you, Mr. Chairman. It is a pleasure to be here to update you on the implementation of the new Medicare prescription drug benefit and I want to particularly thank you for sitting here and listening to my opening statement. I appreciate it. As a result of extensive--

MR. BILIRAKIS. Somebody has to do it.

DR. MCCLELLAN. Somebody has got to do it, that is right. As a result of extensive outreach efforts, enrollment is off to a strong start in the prescription drug benefit. More than 25 million Medicare beneficiaries now are receiving prescription drug coverage and we particularly applaud the pharmacists for their tremendous help with this new benefit. The number of Medicare beneficiaries continues to grow at the rate of hundreds of thousands of new enrollees in the prescription drug benefit each week. Over 5.5 million people have enrolled individually in prescription drug plans. The vast majority of the new enrollees in these stand-alone prescription plans have chosen plans offering something other than the standard drug benefit designed by Congress.

Many beneficiaries have chosen coverage with low or no deductible, with fixed co-payments instead of co-insurance; it is very predictable, and coverage in the coverage gap, as well as other additional benefits made possible by the choices available. Because of strong competition among the drug plans, the Medicare prescription drug coverage is costing much less than expected. Premiums are one-third lower on average and seniors are saving about $1,100 on average on their annual prescription drug cost. A new CMS analysis demonstrates that Medicare beneficiaries with common chronic conditions can save a substantial amount on their drug bills by enrolling in a drug plan compared to what they would pay without this coverage.

For example, people with Medicare who select the lowest cost plan in their area can save an average of 57 percent on their drug costs with savings available because of lower prices, including prices that are usually significantly lower than the Medicaid prices negotiated by government. Savings increase to 70 percent or more when beneficiaries use generic versions of their drugs, drugs that have the same active ingredient and work in exactly the same way. Savings can be over 80 percent or more when they switch to drugs in the same class that work in a similar way to the drug they are taking now, as Consumers Union and many other consumer groups have recommended.

The analysis also demonstrates that a range of plans available to beneficiaries can provide large savings, as well. In other words, beneficiaries can get substantial savings just by focusing in on the specific kind of drug plan that they want. Taxpayers and States are saving, as well. Since last July, the projected cost of the drug benefit has dropped by $30 billion over the next five years. States will spend $37 billion less than projected over the next 10 years and we recently announced $700 million in additional State savings this year alone. In fact, the total spending on prescription drugs in this country is now projected to be significantly lower because of the drug benefit, even as seniors are getting millions more prescriptions filled at a much lower cost.

Many beneficiaries with limited incomes and resources can save even more; 95 percent of the cost of their prescription drugs on average by applying for the low-income subsidy. You will hear more about that from someone who is taking advantage of the subsidy on the next panel. To identify and enroll beneficiaries who can qualify for this extra help, CMS has entered into a new agreement with the National Council on Aging. Through this agreement the NCOA will refine lists of beneficiaries to improve the ability to target outreach and enrollment. NCOA is also reviewing alternative strategies to supplement and improve the ongoing and future outreach efforts for low-income subsidy beneficiaries.

Now, while the vast majority of beneficiaries are using their prescription drug coverage effectively and while plans are filling millions of prescriptions each day, some people who enrolled or switched plans late in the month, especially dual eligible beneficiaries, have had problems when filling their prescriptions the next month. The information systems didn't have time to sufficiently reflect these changes. To make people aware of how they can avoid these problems, we have undertaken an education campaign. We are encouraging people to enroll early in the month to get coverage the next month. We have updated our online enrollment center messages. We have modified the scripts that our call centers use when people call us at 1-800-MEDICARE and we are working with pharmacists, States, and advocacy organizations to convey this important information.

We are working to prevent any such problems with switching plans and late enrollment in the future and we don't want anyone with Medicare to leave the pharmacy without the prescriptions they need. Almost everyone who joins or changes plans before the 15th of each month, when they sign up on their own, will get their prescriptions filled quickly and conveniently the next month. This allows Medicare and the plans time to update systems and plans time to mail important documents

like proof of enrollment and a membership card before the coverage begins.

Due to the difficulties that some dual eligible and other low-income beneficiaries face, States, in many cases, have activated their State payment systems to ensure that people receive their medicines. Through a temporary demonstration program, Medicare is reimbursing States for supporting the transition of dual eligible beneficiaries to their Medicare drug coverage. We will reconcile drug payments with the prescription drug plans and pay any differential between the drug plan reimbursement and Medicaid costs because in many cases the Medicaid program is paying higher prices than the new competitive drug plans. We will also pay for State administrative costs.

States are widely participating in this program. Of the States that are participating, the vast majority either did not activate their State payment system and are seeking only reimbursement for administrative expenses, or they have a very low rate of using their State claim systems. Most States are using their State billing system for only a small share of prescription drug claims, averaging one prescription or less per pharmacy each day. In Florida, during the time of this reimbursement program, fewer than a hundred prescriptions have been filled through the State system, for example. Most States are working closely with us, using our backup systems and caseworkers, if needed, to make sure that all beneficiaries are getting the drugs they need and in the vast majority of cases, avoiding the need for State billing.

As we continue the implementation of this new program, we are learning from our past experiences. We will apply these lessons in the future in the guidance we provide to the plans, physicians, pharmacists, and our other partners. I want to thank you again for this opportunity to discuss our progress during the first two months of the most important new benefit in Medicare in 40 years, the new and overdue prescription drug coverage. While we are pleased that millions of Medicare beneficiaries are getting their coverage used effectively every day, getting prescriptions filled every day, we are going to continue working to ensure that everyone with Medicare can use this coverage smoothly and effectively. I am happy to answer any questions that you all may have.

[The prepared statement of Hon. Mark McClellan follows:]

PREPARED STATEMENT OF THE HON. MARK MCCLELLAN, ADMINISTRATOR, CENTERS FOR MEDICARE & MEDICAID SERVICES

TESTIMONY OF

MARK B. McCLELLAN, M.D., Ph.D.

ADMINISTRATOR

CENTERS FOR MEDICARE & MEDIC[illegible]

BEFORE TH[illegible]

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NEW[illegible]TION DRUG[illegible]NE[illegible]

March 1, 2006

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Chairman Deal, Rep. Brown, distinguished members of the Subcommittee, thank you for the opportunity to update you on the new Medicare prescription drug coverage, and especially the steps we are taking to address transition issues. The vast majority of beneficiaries are using their coverage effectively, plans are filling over a million prescriptions a day, and each week hundreds of thousands more beneficiaries are enrolling in the new program.

Prescription drugs are a critical component of 21st Century medicine, but until recently the Medicare program did not include an outpatient prescription drug benefit. Now Medicare's new prescription drug benefit provides seniors and people with disabilities with comprehensive prescription drug coverage, the most significant improvement to Medicare coverage in 40 years. Millions of seniors and people with disabilities are already using this benefit to save money, stay healthy, and gain peace of mind, rather than simply paying the bills when they get sick.

Because of strong competition in the prescription drug marketplace, there has been slower drug cost growth in recent years, due in part to improving generic drug availability. Consequently, the new Medicare prescription drug coverage is costing much less for beneficiaries, taxpayers, and the States than anticipated. For example, beneficiary premiums are now expected to average $25 a month – down from the $37 projected in last July's budget estimates – and the overall cost to taxpayers for 2006 has dropped about 20 percent since the July 2005 estimate, according to the CMS Office of the Actuary. The savings result from lower than expected costs per beneficiary; projected enrollment in the drug benefit has not changed significantly. For the 10-year period from 2006-2015, the net total cost to Medicare of the drug benefit is now estimated to be about $130 billion less - $797 billion compared to an estimated $926 billion last year.[1] In addition, the state phase-down contributions are now projected to be $37 billion (about 27 percent) less over the 10-year period.

[1] CMS Office of the Actuary , February 9, 2006. Actual future costs of the benefit could be higher or lower than these updated estimates.

We already are hearing reports from our partners about the cost savings people with Medicare are experiencing. For example, Barbara from Lynchburg, Virginia, with the assistance of a community based organization, selected and enrolled in a plan that will save her $2,400 a year on her drug costs.[2] On average, seniors who previously did not have drug coverage are saving $1,100 on their annual drug costs by selecting a plan in the new Medicare prescription drug benefit, compared to paying directly for their drug costs.[3] The savings for beneficiaries who now qualify for the low-income subsidy (and who did not previously receive Medicaid drug coverage) is substantially greater, amounting to over 95 percent of drug costs on average.

While considerable progress has been made, change of this magnitude in such a short time span is bound to encounter some difficulties. CMS is very concerned about anyone who has experienced problems in obtaining their medicines. We make no excuses for the problems. They are important, they are ours to solve, and we are finding and fixing them.

Specifically, a significant portion of the problems for beneficiaries centered on certain beneficiaries who enrolled or switched plans late in a month, particularly dual eligible beneficiaries, those individuals who qualify for both Medicare and Medicaid. We are taking action to address these issues so that all beneficiaries enrolled in a Medicare prescription drug plan can obtain their medications without incident. CMS also is working to correct data transmission problems between Medicare, health plans, pharmacists, and the States.

Customer service also is a priority, and we are working to eliminate any delays or other difficulties for those needing assistance. In order to assist pharmacists, who have been outstanding in their commitment to service, CMS is working to ensure they have the resources and support they need. CMS also is coordinating with the States that used their state reimbursement systems to pay for prescriptions that should be paid by the new Medicare prescription drug plans. CMS believes they should be reimbursed for any

[2]Medicare Today written testimonial, January 25, 2006.
[3] President's Budget FY2007, February 8, 2006

legitimate expenses beyond the payments they will receive from the plans and is doing so through a new demonstration program. We also are monitoring plan activities and will use our enforcement measures, if necessary, to ensure they are adhering to the requirements of participating in the Medicare prescription drug program. These efforts build on the preparations that were made long before the January 1, 2006 launch of the Medicare prescription drug benefit.

CMS and Partners Conduct Extensive Outreach and Education for Beneficiaries
CMS worked with the plans, pharmacists, States, and hundreds of other partners leading up to the start of the drug benefit to educate beneficiaries and their caregivers about the Medicare prescription drug benefit and help people understand how to make decisions about the prescription drug plans based on cost, coverage, convenience, and peace of mind. These efforts are continuing with particular emphasis on rural areas and beneficiaries who may qualify for the low-income subsidy.

In addition to print, radio and television advertisements, CMS has a multi-pronged approach to raise awareness and assist beneficiaries and their caregivers in making decisions about prescription drug plans. President Bush, Secretary Leavitt, and I, along with CMS' regional office staff, have traveled over 200,000 miles across the country in a mobile office bus to form grassroots partnerships that help people with Medicare make an informed decision about prescription drug coverage. About 73 percent of these mobile office stops have taken place in rural communities throughout the country. Many Members of Congress have served as honorary chairs for these events and we appreciate their involvement in forging over 240 grassroots community and statewide networks, each led by a community partner. The mobile office reached rural areas across the country to complement our dedicated funding for research and outreach to rural areas. To date, 235 Members or their staff have participated in events and we welcome your involvement in future activities to reach beneficiaries, especially those who can benefit from the low income subsidy.

In addition to the mobile office events, the CMS regional offices along with state health insurance assistance programs, senior advocacy organizations, and agencies on aging have held thousands of information and enrollment events. Since January CMS and its partners have hosted over 2,000 events. These organizations also are providing personalized counseling on request to help beneficiaries enroll in plans that best meet their needs. CMS worked with the Social Security Administration and various organizations to provide training and conduct outreach to beneficiaries who may qualify for low-income assistance. These organizations include for example, the Access to Benefits Coalition, Case Management Society of America, the National Association of Community Health Centers the Visiting Nurses Association of America, AARP, and CARxE (a private group focusing on outreach to low income beneficiaries through faith-based efforts). In addition, CMS provided special training for social service coordinators to help them counsel low-income seniors. CMS also worked with social workers and many sub-specialty organizations such as the Oncology Social Workers, who have a desire to help their client base and their community make decisions about the Medicare prescription drug benefit.

CMS also has a contract with the National Association of Area Agencies on Aging (n4a) to target beneficiaries and their caregivers that are hard to reach including minority, low-income, limited English speaking, homebound, and rural populations. Strategies included contracting with Aging Network community-based organizations and nine National Aging Organizations with local affiliates to conduct outreach to low-income populations. The nine organizations include the National Association of Nutrition and Aging Services Providers, Meals on Wheels Association of America, National Hispanic Council on Aging, Asociacion Nacional Pro Personas Mayoras, The National Alliance for Hispanic Health, National Center and Caucus for Black Aged, Inc., National Asian Pacific Center on Aging, National Adult Day Services Association, and National Council for Independent Living.

In addition to events around the country, we are providing a number of ways for people to get information. The *Medicare & You 2006* handbook included information about the

new prescription drug coverage. Also, the 1-800-Medicare helpline (including TTY assistance) and www.medicare.gov are available 24-hours a day with assistance in English and Spanish, and help available in many other languages as well.

Strong Enrollment Continues to Grow

As a result of successful outreach efforts, participation in the drug benefit is off to a strong start. More than 25 million Medicare beneficiaries now are receiving prescription drug benefits and the number of Medicare beneficiaries receiving coverage continues to grow at a rate of hundreds of thousands of beneficiaries per week. This puts us well on track toward the expected enrollment of 28 to 30 million in the first year. This number reflects more than 5.3 million beneficiaries who have signed up individually for prescription drug coverage in the last three months, including 1.5 million who signed up in the last 30 days. The vast majority of the new enrollees in stand-alone drug plans have chosen plans offering other than the "standard" drug benefit. Many beneficiaries chose coverage with a low or no deductible, fixed copayments for most prescriptions instead of coinsurance, and/or coverage in the coverage gap – coverage options made possible by the strong competition in the Medicare drug benefit.

As shown in Figure 1, as of February 13 about 4.9 million people have enrolled individually in a stand-alone prescription drug plan, and more than 400,000 beneficiaries have also newly enrolled in Medicare Advantage (MA) plans that are generally providing more comprehensive and lower-cost drug coverage. About 6.2 million dual eligible individuals also are enrolled in Medicare prescription drug plans, including 560,000 in Medicare Advantage plans, many of whom have more comprehensive coverage than before (for example, about one in four states had limits on the number of prescriptions for Medicaid beneficiaries, and Medicare coverage has no such limits). Another 4.7 million people are enrolled in a Medicare Advantage plan, and this coverage is now much more comprehensive and less costly (previously, while most MA plans provided drug coverage, the coverage generally included caps and other limits). About 6.4 million retirees are enrolled in employer- or union-sponsored retiree plans receiving the Medicare Retiree Drug Subsidy and another 1 million retirees are in employer coverage that

incorporates or supplements Medicare's coverage, so that high-quality retiree coverage has more secure financial support.

Separate from the new Medicare drug benefit, another estimated 500,000 retirees from employers not utilizing the Medicare retiree subsidy are continuing in coverage that is as good as Medicare's. An additional 3.1 million retirees are receiving prescription drug coverage either through TRICARE or the Federal Employee Health Benefits Program (FEHBP).

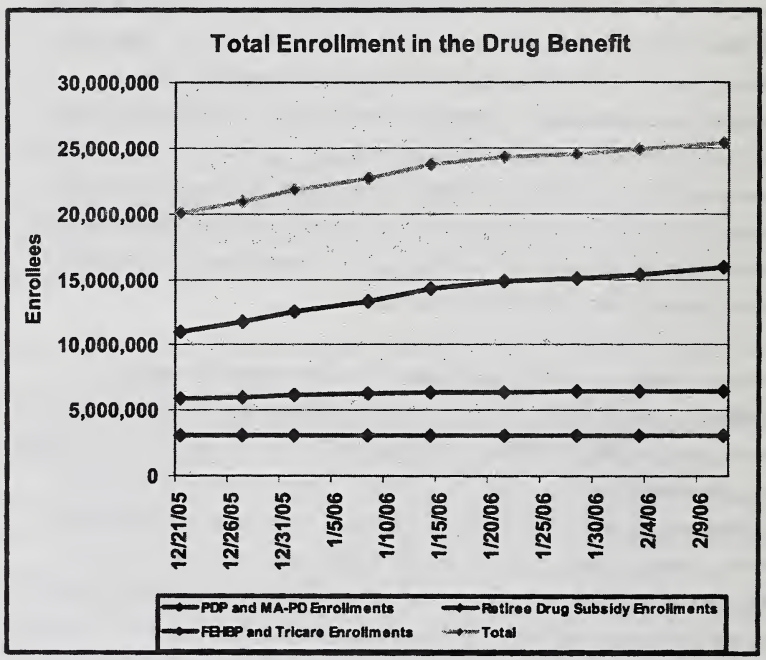

Figure 1: Enrollment in Medicare Prescription Drug Benefit, Medicare Advantage-PDPs, the Retiree Drug Subsidy, FEHBP, and TRICARE[45]

[4] MA-PDP enrollments are under-reported as plans update CMS records concerning the movement of beneficiaries from MA to MA-PD plans.
[5] Retiree Drug Subsidy enrollment numbers between 12/27/05 and 1/8/06 are estimates

Although more than 25 million Medicare beneficiaries now have prescription drug coverage and CMS is encouraged by the strong enrollment numbers, outreach efforts will continue to promote enrollment for those who will benefit from this program and who have not yet enrolled. The open enrollment period for the new drug benefit continues until May 15, 2006 and we are encouraging and helping people with Medicare to review their options and select a plan that works best for them.

Competition Helps Lower Drug Prices

Competition among sponsors of Medicare prescription drug plans has helped reduce prescription drug costs for Medicare beneficiaries, which has been illustrated by a number of recent studies.

CMS analyses demonstrate that Medicare beneficiaries with common chronic conditions can save a substantial amount on their drug bills by enrolling in a Medicare prescription drug plan (PDP) compared to what they would pay with no drug coverage.[6] For instance, people with Medicare who select the lowest-cost plan in their area can save up to 71 percent off the prices they would pay without prescription drug coverage.

The analysis also demonstrates that a range of plans available to beneficiaries can also provide large savings. This is true for a very broad range of plans if beneficiaries are willing to use generic versions of their existing drugs, when available, which are required to have the same active ingredients and work in the same way as the brand-name drug. These results indicate that beneficiaries can see substantial savings on their drug bills by focusing on a few plans with the features they prefer – such as a low premium, or fixed copayments, or coverage in the gap.

Even larger savings are possible – as much as 83 percent – by switching to drugs in the same class that work in very similar ways to a beneficiary's current brand-name drug. For example, there are many drugs available that work in very similar ways to treat

[6] CMS Office of Policy, Analysis of Savings Available Under Medicare Prescription Drug Plans, March 1, 2006

common conditions like stomach acid problems, Allergic rhinitis, high blood pressure, and high cholesterol levels. According to Consumers Union, considering these drugs can save beneficiaries billions more in drug costs each year.[7] Beneficiaries can get personalized information on these additional savings from medicare.gov, 1-800-MEDICARE, and many of Medicare's partners.

A number of external reports strongly support these findings. For example, the Pharmaceutical Care Management Association (PCMA) released a study in February 2006 indicating that Medicare drug plans offer significant price discounts compared to what beneficiaries would pay without coverage.[8] The study found an average savings for beneficiaries of 35 percent at participating retail pharmacies and 46 percent through mail order pharmacies. Further, for 25 commonly used medications, the PCMA study found savings from 18 percent on brand name drugs at retail pharmacies to 26 percent at mail order pharmacies. In addition, a January 2006 report prepared by the Lewin Group demonstrates that beneficiaries with chronic conditions, particularly those with multiple conditions, will see significant savings on their prescription drug bills by enrolling in a Medicare prescription drug plan.[9] For example, while beneficiaries with one chronic condition will save on average $396 on their medications with Medicare drug coverage, accounting for 26 percent of their current drug spending, those with four or more conditions will save an average of $1,774, or 41 percent, on their medications. These studies have made "apples to apples" comparisons of drug prices available at retail pharmacies instead, for example, of common, but misleading, comparisons between retail pharmacy and mail-order prices. For this reason, in their recent forecast of prescription drug spending trends, the independent Medicare actuaries have concluded that overall drug spending will be slightly lower as a result of the Medicare drug benefit, even though

[7] Consumers Union, "Helping Medicare Beneficiaries Lower Their Out-of-Pocket Costs Under the New Prescription Drug Benefit," December 14, 2005.

[8] "Medicare Drug Discounts Real & Holding Steady", Pharmaceutical Care Management Association, February 7, 2006.

[9] The Lewin Group, "Savings From the Medicare Drug Benefit for Beneficiaries with Chronic Conditions," Prepared for National Health Council, January, 2006.

Medicare beneficiaries will be able to fill millions more prescriptions than would have been possible without the drug coverage.

Market Forces Drive Plan Simplification

In addition to reducing the cost of prescription drugs, market forces are working to simplify the plan offerings resulting in more attractive alternatives for beneficiaries. For example, plans could vary their deductible from $0 to $250 and 85 percent chose to offer plans with no deductible. CMS also is asking for comment on whether plans can more effectively serve the diverse Medicare population with a more limited number of choices. We recently asked for comment on whether to limit the number of plans for 2007 from no more than three to no more than two per region for each sponsor.

CMS also is working to make it as easy as possible for beneficiaries to review the different options available to them in selecting a plan. As individuals have different needs and preferences when it comes to their health-care coverage, presenting plan features in a way that facilitates comparison on the basis of plan attributes and performance indicators will make it easier for beneficiaries to choose the plan with the features that are most important to them. In our research of Medicare beneficiaries, overall drug cost is generally the most important single factor to most beneficiaries. Other important plan attributes include the premium, the deductible, whether the plan provides a set copayment amount or a percentage coinsurance, and more comprehensive coverage in the "coverage gap." Breadth of formulary (some beneficiaries prefer "open" formularies) and access to a particular pharmacy are also important to many beneficiaries. The substantial savings available to beneficiaries from many plans mean that beneficiaries can focus just on a small number of specific plans that have the features they most prefer. Medicare and its partners are already making available personalized information on these plan features, and we are working with many outside organizations to enhance the resources available to beneficiaries to identify the specific plan or plans that are a good fit based on their own preferences.

Addressing Coverage Problems for Dual Eligible and Late Enrollees

Since the start of the enrollment period, more than 2.1 million people have enrolled in the Medicare prescription drug program through an on-line enrollment center with tens of thousands of new on-line enrollments daily. Many more beneficiaries switched plans, or (for dual eligible and other lower-income beneficiaries) had plans switched on their behalf by a state. CMS experienced a substantial surge in enrollment and plan switches near the end of 2005. As shown in Figure 2, both visitors to the prescription drug plan on-line enrollment center and enrollments rose steadily throughout December and peaked at the end of the month with over 100,000 enrollments on both December 29 and 30, 2005. Some switches and late enrollments also occurred in late January.

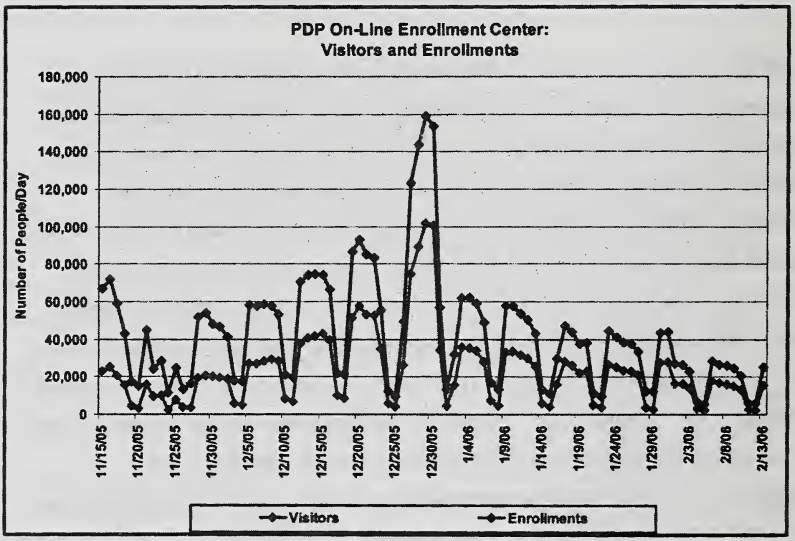

Figure 2: Prescription Drug Plan On-Line Visitors and Enrollments

Some people with Medicare prescription drug coverage who enrolled or switched plans late in the month, particularly dual eligible beneficiaries, experienced problems when attempting to fill prescriptions early the next month. The information systems did not have sufficient time to reflect this change and accommodate the fact that hundreds of

thousands of beneficiaries switched plans in the last half of December, as reflected in our early January problems.

CMS is working to minimize problems associated with switching plans and late-month enrollments in the future as we do not want anyone with Medicare who is enrolled in a plan to leave the pharmacy without the prescriptions they need. Because it takes time to process enrollments, there are real advantages to joining a Medicare drug plan at the beginning of the month. Almost all who join or change plans before the 15th of each month will get their prescriptions filled quickly and conveniently beginning with the next month. Early enrollments allow Medicare and the plans time to update systems and plans time to mail important documents (e.g., confirmation letter, membership card, welcome package) before the effective date of coverage. Early enrollees can get the most out of their coverage from the first day it is effective. Enrollees who join later in the month may have to spend extra time at the pharmacy to get their prescriptions filled, especially if they try to use their coverage shortly after enrolling.

To make people aware of the advantages of enrolling early in the month, CMS updated its online enrollment center messages and modified scripts used in our call centers, and we are communicating this information to pharmacists, States, and advocacy organizations. These educational activities may already be having an effect: In the last week of January, only about 24,000 people switched plans, down from the hundreds of thousands of individuals who were auto-enrolled and elected a different plan in the last half of December. This reduced the problems of incomplete information at the pharmacy counter significantly at the start of February.

To improve the information available to Part D plans about their dual eligible and low-income members, CMS provided the Medicare prescription drug plans with several files during January of all the people with Medicare who are either dual eligible or qualify for the low-income subsidy. We have continued to provide such sources of information to confirm plan enrollments in February. The plans use this data to cross-check with their own records to correct any errors or omissions. As plans process these data and improve

their beneficiary information databases, the workload of the pharmacists is reduced and the vast majority of dual eligible individuals get their drugs more smoothly. With correct data, pharmacists identify plans in which dual eligible individuals are enrolled and ensure that correct and appropriate copayments are charged to the individual with Medicare. As a result of these data exchanges, we expect fewer problems for people with Medicare at the pharmacy.

CMS Automatically Enrolled Full Benefit Dual Eligible Individuals into Plans

To prevent a lapse in prescription drug coverage for full benefit dual eligible individuals, CMS worked diligently to make sure they were enrolled in a Medicare prescription drug plan before January 1, 2006. In November 2005, any individual who was a full benefit dual eligible for even one month, beginning in March 2005, was automatically enrolled in a prescription drug plan. CMS understood that the dual eligible population is typically the hardest to reach and preparation was necessary. To that end, CMS sent letters in May to all full benefit dual eligible individuals to inform them of their upcoming auto-enrollment into a prescription drug plan. Then, in the fall, CMS sent these individuals a letter that informed them of their new plan and the option to choose another plan if they were not satisfied with the auto assigned plan option. In addition to the letters, individuals can call 1-800-MEDICARE to find out the plan in which they have been auto-enrolled.

Also, while other individuals generally have the opportunity to change plans only at the end of the calendar year, dual eligible individuals have the opportunity to change plans at any time. This flexibility allows them further opportunities to select a plan that best meets their needs.

CMS also has worked with States to identify and auto-enroll individuals who are about to become full-benefit dual eligible prior to the end of their Medicaid drug coverage to work toward a seamless transition on an on-going basis. This includes those Medicaid individuals who will age into Medicare or who will reach the end of the 24-month Medicare disability waiting period.

Point-of-Sale System Facilitates Enrollment

CMS has made and continues to make its best effort to identify and auto-enroll full benefit dual eligible individuals prior to the effective date of their Medicare Part D prescription drug coverage eligibility. However, it is possible that some individuals may go to pharmacies before they have been auto-enrolled in a prescription drug plan. For this reason, in anticipation of the shift of drug coverage from Medicaid to Medicare for full benefit dual eligible individuals, CMS developed a process for a back up plan at the pharmacy point-of-sale (POS) to ensure these individuals experience no gap in coverage. CMS contracted with WellPoint, a national prescription drug plan, to provide prescriptions at the pharmacy POS and enrollment into a WellPoint prescription drug plan for full benefit dual eligible individuals who had not been previously enrolled in a Medicare prescription drug plan.

Through this point-of-sale system, beneficiaries who present at a pharmacy with evidence of both Medicaid and Medicare eligibility, but without current enrollment in a prescription drug plan, can leave the pharmacy with a filled prescription and the claim for their medication submitted to a single account for payment. A CMS contractor will follow up to validate eligibility and facilitate enrollment of the full-benefit dual eligible individual into a prescription drug plan.

CMS has provided information on the WellPoint system to pharmacy associations, plans, and individual pharmacies. This information describes how the process of POS-facilitated enrollment starts at the pharmacy with the pharmacist verifying dual eligibility and billing a special WellPoint account in order to ensure that the individual with Medicare receives the prescription.

CMS Worked To Achieve a Smooth Transition in Long Term Care Facilities

CMS is committed to ensuring that the 1.6 million people in the 15,800 long term care (LTC) facilities nation-wide continue to receive the medications and pharmacy services they need under the new Medicare prescription drug coverage without interruption. Many "private pay" patients in LTC facilities are getting many thousands of dollars

worth of help with their drug costs for the first time ever. A majority of individuals in long term care facilities are Medicare beneficiaries, and many of them also are eligible for Medicaid. Individuals in LTC facilities represent a unique and vulnerable population because many have cognitive and/or functional impairments. This population typically has multiple co-morbidities, the highest utilization of drugs, with an average of nine medications per day, and the highest spending for prescription drugs compared to other people with Medicare.

Cognitively impaired individuals represent a particularly difficult group to educate about their enrollment options. Much of this population, specifically full benefit dual eligible individuals, was auto-enrolled into the new prescription drug benefit. CMS encouraged nursing homes to determine into which plans their residents were auto-enrolled prior to January 1, 2006. As part of this initiative, CMS established dedicated call lines and overnight mail options to allow nursing homes to fax and mail beneficiary information to CMS customer service representatives (CSRs). This strategy enabled CMS to help nursing homes identify the plans for more than 500,000 residents. Pharmacists used the electronic eligibility and enrollment verification (E1) system (described below) to identify the remainder. By notifying plans that their dual eligible enrollees reside in nursing homes, and by assisting LTC facilities in working to correct cases where copay information is not up to date, CMS is ensuring nursing home residents have access to Medicare drug coverage without premiums and copays.

CMS Provides Education on the Transition Policy

While the new prescription drug plans are required to cover medically necessary prescriptions, CMS required plans to establish an appropriate transition plan for all new enrollees to address situations where a beneficiary's prescribed medications are not on the plan's formulary. The transition policy allows beneficiaries to get a temporary supply of their current drugs while they determine whether a similar on-formulary medicine will work for them. Recently, we asked all plans to extend the transition period to March 31, 2006 Additionally, CMS recommends that transition plans address unanticipated

enrollee transitions when individuals need to change treatment settings due to a change in their level of care.

CMS guidance to plans includes a 90 to 180 day transition period for LTC facilities to accommodate the needs of Medicare beneficiaries residing in those facilities. In general, plans are providing 90 day transition periods with many offering the option of extending to 180 days. However, the LTC emergency first-fill policy is unique to this setting and continues throughout the entire year for any off-formulary prescription written. In addition, plans are required to cover drugs as prescribed during the 7 to 14 days allowed for initial exceptions and appeals processes.

It is of vital importance that beneficiaries, caregivers, advocates, providers, and pharmacists understand the most expeditious and successful way to transition from drugs on Medicaid formularies to drugs on the plan formularies. Therefore, CMS is providing appropriate education materials to people with Medicare, caregivers, advocates, providers, and pharmacies. These materials will explain the basics of how to successfully transition from one medication to another, the steps that should be taken, and tips for beneficiaries on how to work with their physicians and pharmacists during the transition. CMS also will use earned media, teleconferences and Open Door Forums to provide information about transition policies. CMS is encouraging the new Medicare prescription drug plans to also provide information on how people can transition to an alternate medication.

Correcting Initial Data Transmission Issues

Transmitting accurate and timely beneficiary and plan data has been paramount in ensuring the prescription drug benefit could be implemented January 1, 2006. However, information sharing between CMS, the States, and the Medicare prescription drug plans has not always been perfect. Although smooth and timely data transfers among Medicare; our drug plans, Medicare Advantage plans, and retiree plans; and 56 States and territories have occurred for most beneficiaries, we have been working intensively to improve these data handoffs. When information is not exchanged smoothly, the lag time

increases between when a beneficiary enrolls in a drug plan and when necessary information (particularly dual and low-income subsidy information) becomes current in both the plan and CMS systems. As a result, some people with Medicare prescription drug coverage were not included in the system, which caused problems for them when they attempted to fill a prescription the first time. CMS is working diligently to ensure our data systems interact properly with other systems so that data information exchanges are accomplished smoothly and completely.

As an additional safeguard in mid-January, CMS contracted with Electronic Data Systems (EDS) to help CMS work together with the plans, States, and pharmacies to resolve challenging data translation issues. EDS has assisted with our implementation of steps to improve communications and understanding among CMS, plans, and states to support smooth transactions. EDS is providing regular feedback and recommendations to CMS and we expect them to complete a further review with additional recommendations by the end of March. We are working with plans, States, and our other partners to implement their recommendations on an ongoing basis, achieving the goals outlined below by mid-April.

Many plans are sending CMS daily files reflecting their enrollment transactions, and reliably use our responses to these daily files as well as our weekly summaries of the results for timely and accurate updates of their systems. Our goal is that plans covering 90 percent of the enrollee population will use these daily and weekly data transfer processes successfully to reduce lags in obtaining updated beneficiary information.

To check and further assure the accuracy of the information exchange between plans and CMS, we have sent special updated data files, including full copayment information, on the full dual and low-income subsidy enrollment in plans. Our goal is to achieve, by ten days before a new coverage month begins, at least a 95 percent match for enrollment and LIS copayment information on applicable beneficiaries between Medicare and the plans. As a result, adjustments and additional batch data processing by plans near the end of the month can be limited, while addressing the needs of late-enrolling beneficiaries. We

have already seen the match rate for plan enrollment and copayment information increase since mid-January, exceeding 90 to 95 percent before the end of the month.

CMS continues to work on matching data files with the States, so that appropriate information for dual eligible individuals is available to CMS, plans, and pharmacists. We obtained a match rate of greater than 99 percent for duals submitted by the States in the fall of 2005, and we expect to maintain a high match rate.

Planning Started Early for Information and Technology Requirements

Planning for the information technology to support the implementation of the Medicare prescription drug benefit began in 2004 with CMS identifying the key functions affected by the new law and beginning development of a large-scale, integrated computer system. Staff created and modified a variety of complex, integrated systems that currently interact with the private and public sectors to implement the new benefits. CMS ensured that more than one dozen critical systems development efforts were implemented in time to meet MMA-legislated deadlines. In conjunction with its business partners, CMS developed innovative solutions and leveraged existing business and systems relationships, such as using the existing pharmacy transaction processing network, to assist with the coordination of the various prescription drug benefit plans covering people with Medicare.

These IT systems support the key critical business processes that CMS uses to manage the Medicare Advantage and prescription drug benefit programs. The integrated system provides CMS with the ability, among other things, to enroll people with Medicare into prescription drug plans, make payments to plans, and ensure that beneficiaries receive their drug coverage. In preparation for MMA implementation, CMS refined its systems to accept, process, and reply to plan transactions on a daily basis, a far quicker turnaround than the monthly reporting cycle used under the Medicare Advantage program. CMS is now working with plans to change their operational processes to incorporate this faster processing and reporting cycle.

The integrated information technology system also allows CMS to pay the Retiree Drug Subsidy to approved plan sponsors and track True-Out-of-Pocket Expenses (TrOOP – costs borne by the enrollee) for people with Medicare. In addition, the updated systems ensure the correct premium amount is either paid directly to the plan or provided to the Social Security Administration to withhold from a beneficiary's Social Security check. Through contracts with telecommunications clearinghouses that currently service the majority of retail pharmacies, the pharmacies will be able to perform real-time eligibility determinations and will be able to route claims to primary, and if applicable, secondary plans for proper adjudication to accurately coordinate benefits. The new and modified systems also were designed to ensure only authorized individuals have access to Medicare information.

CMS worked closely with industry experts to implement nine system modules. Implementation included application development and integration efforts, system engineering activities, and validation and testing. In order to meet the deadlines, CMS worked creatively and collaboratively to compress what would ordinarily be an 18 to 24-month systems development process. CMS ensured that the necessary computer and network capacity and capabilities were in place as the CMS IT applications came online.

These enhancements included:

- providing capabilities for more than 400 new CMS business partners to connect to CMS systems over the Internet,
- providing advanced technology for secure file transfers, and
- implementing a new user id/password management system.

CMS implemented backup and parallel support systems to minimize any vulnerabilities and also oversaw the implementation of a secure, Internet-based computing environment in the CMS data center. If these systems had not come online on schedule, CMS would not be able to enroll beneficiaries or pay the health plans that are administering the new benefit. CMS set new standards for documenting requirements, program management,

managing change, testing systems, and documenting and ensuring that system development life cycle reviews were undertaken.

Providing High Level Customer Service

CMS understands that people with Medicare, their families, doctors, and pharmacists will have questions about the new Medicare drug benefit. It is unacceptable that people have experienced wait times of 30 minutes or more to get the vital information they need to get prescriptions filled. These problems were caused in part by the data translation problem, late enrollment, and plan switching mentioned earlier. The problems also were caused by inadequately staffed customer service centers. CMS is working to improve the situation and ensure accurate information is available in a timely manner to those seeking assistance.

CMS Improves 1-800 MEDICARE Call Center to Reduce Wait Times

CMS' 1-800 MEDICARE Call Center has customer service representatives (CSRs) available to answer Medicare questions 24 hours a day, seven days a week. As shown in Figure 3, call volume to 1-800-MEDICARE peaked around 400,000 calls when enrollment began on November 15, 2005 and again in early to mid-January. On average, callers have experienced wait times of less than two minutes from mid-November to mid-February, with longer waits sometimes occurring during peak call periods.

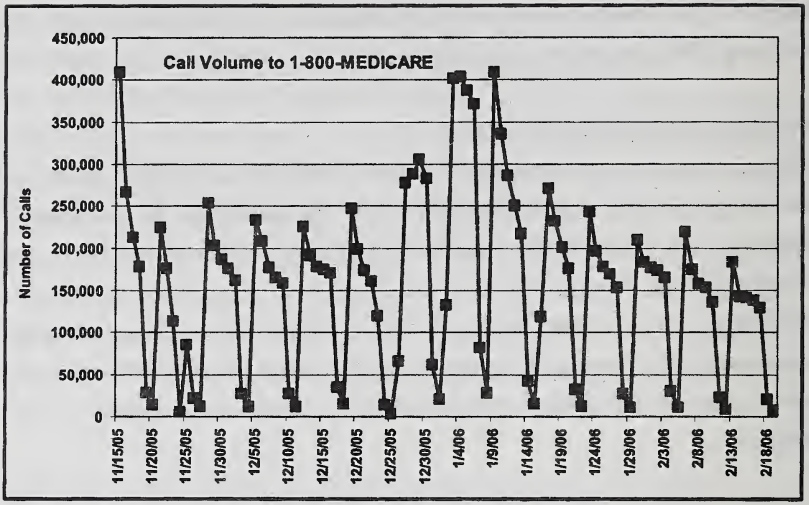

Figure 3: Call Volume 1-800 MEDICARE

CMS has increased the number of CSRs from 3,000 in June of 2004 to as many as 7,800 to handle beneficiary calls. We have also acquired additional infrastructure including telephone lines, workstations, and seats at call center sites. We have refined our CSR scripts by reducing redundant information, indexing scripts for quick access, and including probing questions to help the CSRs better identify the caller's concerns.

CMS has implemented a major enhancement through the use of Smart Scripts, which provide the CSRs with an easily followed path of responses to the most frequently asked questions. Smart Scripts are a new type of script that has hyperlinks built into the body of the text that when activated will take the CSR directly to related information about that subject. In addition, we have CSRs participate in the content workgroups for the actual development of scripts and job aides. CMS also has implemented a CSR feedback system and streamlined our approval process for updating the scripts in a timely manner to respond to the changing needs of our customers or to incorporate policy updates.

CMS hired and trained additional staff to exclusively use the Prescription Drug Plan Finder tool to handle only prescription drug plan calls. All CSRs receive one week of classroom training followed by two or three additional days of practice calls, simulation, quality monitoring, and follow-up coaching to ensure peak performance. CSR certification with a written examination and test calls is required prior to taking live calls. Calls are being handled on an in-bound basis and steps CMS has taken to strengthen the call centers' capabilities and reduce wait times have made it possible to address beneficiaries' concerns as they arise.

CMS customer satisfaction surveys indicate that the bulk of callers who interact with our CSRs, 84 percent, are satisfied with their experience. They are particularly pleased with how courteous and patient the CSRs are (rated at 97 and 95 percent, respectively). These responses came not only from people with Medicare, but also friends or relatives calling on their behalf, who made up 48 percent of callers during December, 2005.
In addition to beneficiary satisfaction surveys, CMS also evaluates the 1-800-MEDICARE CSRs through "mystery shopping" to ensure they are providing accurate and complete responses to callers. "Mystery shopping" calls are made to CSRs by an independent specialized quality evaluation contractor who has developed scenarios and scripts to measure the CSRs on various topics to determine if CSRs are being "fully responsive." A response is considered "fully responsive" if all key points are conveyed to a caller. The independent contractor consistently has found that the information provided is fully responsive most of the time and that an inaccurate response occurs less than 1 percent of the time.

CMS' Medicare website, www.medicare.gov, has also been a source of useful information for people with Medicare. Since the first of the year, our frequently asked questions have been accessed more than one million times. CMS also has responded to more than 12,500 e-mails received through the site, with 93 percent of them being resolved satisfactorily in the first response.

CMS Works with Plans to Improve Their Customer Service

In addition to this significant strengthening of our 1-800-MEDICARE capabilities, we have issued guidance to the plans, instructing them to increase the numbers of CSRs in their own call centers and take other necessary steps to provide timely and effective responses to inquiries from enrollees and health professionals. Plans have responded and reported significant increases in the number of CSRs in their call centers, and as a result, plan performance has improved. For example, in the beginning of January, wait times for beneficiaries contacting call centers for nine major plans averaged close to 12 minutes, dropping to just more than 6 minutes by the end of the month. For pharmacists, average wait time has fallen to less than 1 minute for high volume pharmacy lines.

While many plans are now providing timely phone access, some have not responded adequately. Therefore, CMS has increased monitoring of plans' call center activities to help assure a high level of performance. We are surveying all prescription drug plans to assess whether they provide correct information to beneficiaries and pharmacists within a reasonable time. We expect continuing improvements, as we address systems and data transfer issues. We expect plans to generally answer calls within an average response time of five minutes, and while many plans have already made major steps toward this or better performance, we will take further enforcement actions against plans that do not make substantial progress in the weeks ahead.

CMS Provides Caseworkers for One-on-One Counseling

While millions of prescriptions are being filled for people with Medicare, CMS is very concerned about those individuals who are encountering difficulties at the pharmacy counter. This is certainly distressing for those individuals and their caregivers.

CMS has established a system to help resolve urgent issues on a case-by-case basis. CMS has hundreds of trained caseworkers who are working as rapidly as possible to resolve urgent issues to help ensure that people with Medicare get their prescriptions filled. CMS urges people with Medicare or their family members who are having

difficulties to call 1-800-MEDICARE, and if necessary, their case will be forwarded to our caseworkers. Urgent cases have high priority for rapid resolution.

While the number of individual cases is small in comparison to the millions of prescriptions and individuals who are successfully receiving their prescriptions, CMS is committed to ensuring that every individual receives his or her needed medicines, is properly identified, and is charged the appropriate copays in the future.

CMS Takes Steps to Identify Areas of Concern

CMS developed the Complaints Tracking Module (CTM) to capture complaints CMS receives from beneficiaries, providers, or plans about prescription drug plans, pharmacies, subcontractors, and providers. The design of CTM evolved from CMS' experience with the Medicare approved prescription drug cards. Because it is a web-enabled system, it can accept large numbers of daily transactions simultaneously from many users across the Agency. Information can be efficiently exchanged, which allows for quicker resolution and accountability. CMS launched the CTM into production October 3, 2005 and began tracking complaints in January 2006. Although this process is still in the early stages, we have seen a general decline in the number of complaints.

CMS Applauds and Supports the Outstanding Efforts of Pharmacists

Traditionally, the start of a new year is one of the busiest times for pharmacists with new enrollments occurring in commercial and government plans in January. With the launch of the new Medicare prescription drug benefit, the task facing pharmacists was an additional challenge and CMS applauds and supports their tremendous efforts. While the process was relatively smooth for some, other pharmacists had more difficulties in using the new Medicare support tools, and too often have experienced long wait times on plan help lines. But pharmacists are working hard to meet the demands of the new program, and CMS will continue to provide them and their software vendors and support associations with the tools they need to serve their customers.

CMS Provides Dedicated Support to Pharmacists

CMS has provided a number of ways for pharmacists to obtain help in filling prescriptions for plan enrollees. To help pharmacists identify what plan a beneficiary is in, CMS collaborated with pharmacists starting in 2004 to create an electronic eligibility and enrollment query system that operates as part of their existing computer systems. If the enrollee does not have a card or proof of enrollment in a prescription drug plan, pharmacists can use this eligibility system (the E1 system) to obtain information needed to fill the prescription. Using instructions and updates provided by their software vendors, retail pharmacists now generally have the ability to perform real-time eligibility determinations on their existing computer systems. Response times in the system since January 2 have consistently been less than one second. In addition, the number of queries is decreasing, because more individuals have their billing information available through plan cards. For example, as shown in Figure 4, on January 4, this system received nearly 1.5 million inquiries. On January 31st, it had dropped to around 300,000 and since then has declined further.

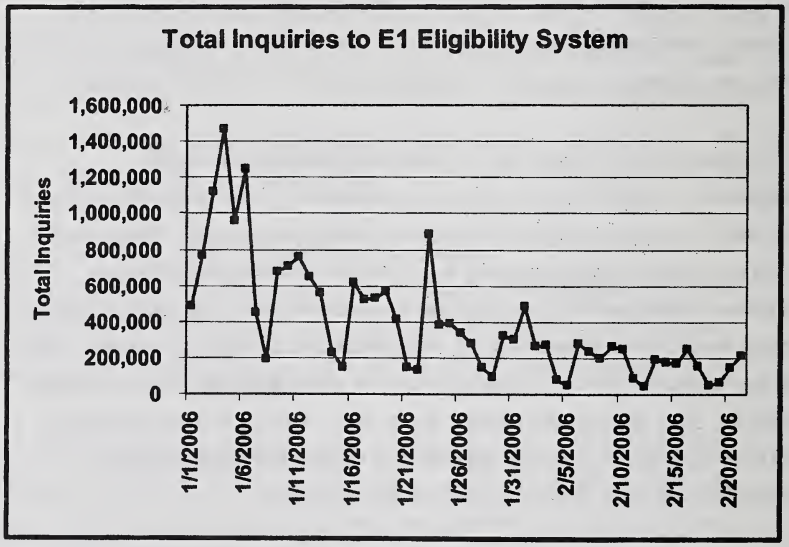

Figure 4: Total Inquiries to E1 Eligibility System

Pharmacists can also call plans directly, on lines dedicated for pharmacists. They can contact Medicare's own CSRs on the toll-free pharmacy support phone lines if need be, and CMS also has specially trained case workers in our regional offices who can intervene in special cases to make sure that enrollees get the medications they need.

To help resolve issues pharmacists encounter in dispensing medications to those newly enrolled in the Medicare prescription drug plans, CMS has increased its call handling capacity at the pharmacist help line and the line is now available 24 hours a day. This increased capacity has reduced the wait time to less than a minute for pharmacists who want to use this mode of communication for eligibility and enrollment determination.

CMS Supports Simplification Initiatives

We have heard concerns from pharmacists about different claims processing and administrative systems used by the various Medicare prescription drug plans. We have helped make sure that plans are aware of the challenges posed by their varying requirements, and we have supported the development of external discussions involving plan and pharmacy representatives to make rapid technical progress towards more standardized electronic responses and prior authorization process for the pharmacists. CMS remains supportive of this initiative undertaken by the plans and pharmacists to improve how the new program operates on a day-to-day basis in the field. This is one of many examples of how various parties are working together to improve the systems.

CMS has also identified a number of business process issues that can be simplified for plans, physicians and beneficiaries. On February 7, CMS posted to its website a model form for beneficiaries to use in requesting a coverage determination. The form was developed with input from the American Medical Association and others and is accompanied by instructions. We have also posted contact information for every drug plan for those wishing to pursue an appeal. To facilitate communications between pharmacists and physicians, we recently posted a form for pharmacists to use to inform physicians that their patient's plan is requiring use of another drug, step therapy, or prior

authorization. We have also encouraged plans to accept prior approval requests by fax, rather than requiring phone calls from physicians, since that is less time consuming for the physicians.

We recently sent information to the plans which will expedite their processes for making sure they are not inappropriately paying for drugs that should be covered under Part B, and we have worked with Epocrates, an electronic prescribing software company, to ensure that their product provides accurate and easy access to plan formularies. We've also held weekly prescribers' conference calls and bi-weekly meetings with the AMA and other organizations to find out what prescribers are experiencing, to supply them with information on our activities and answer their specific questions.

CMS issued a fact sheet February 24, 2006, to provide physicians with updated, practical information about the exceptions and appeals processes. This fact sheet describes the physician's role in these processes and emphasizes the short decision making timeframes.

Finally, CMS has identified a number of areas where plans can improve the data they transmit to the independent review entities that make appeals decisions and will be reiterating or extending its guidance to plans in this area.

Medication Therapy Management

Individuals with more than one chronic disease often require treatment with several prescription medications, which increases their risk for drug related problems. Additionally, they represent a disproportionate amount of health care expenditures. The quality of care for these individuals can be improved and costs can be reduced through Medication Therapy Management (MTM), which promotes appropriate medication use, reduces the risk of adverse events, and optimizes therapeutic outcomes.

Each Part D sponsor must have a MTM program for beneficiaries who have multiple chronic diseases and are taking multiple Part D drugs with annual costs of at least $4000. MTM programs may be furnished by a pharmacist or other qualified provider and must

be developed in cooperation with pharmacists and physicians. This creates opportunities for the pharmacists to play active roles in the MTM services provided.

To realize the full potential of MTM, quality metrics for MTM and related pharmacy services must be developed so that more can be done to support high-quality pharmacy care. To this end, on April 24th, CMS will convene a broad community of stakeholders to encourage the development of a Pharmacy Quality Alliance. Our goal is to help support the development of valid quality indicators and improved measurement of the value of pharmacy services. Similar to our efforts in support of the Ambulatory Care Quality Alliance and Hospital Quality Initiative, we will support a broad stakeholder effort to improve health care quality and patient safety in pharmacy care through a collaborative strategy for:

- measuring performance at the pharmacy level,
- collecting and aggregating data in the least burdensome way to develop better evidence on how pharmacy services can improve outcomes and reduce costs, and
- reporting meaningful information to consumers, physicians, plans and other stakeholders to inform choices and increase the value of Medicare coverage.

This dialogue should highlight the role of the pharmacist as a member of the integrated health care team and recognize the value the pharmacist can bring to the equation of total patient care. CMS may further support this collaborative process by developing a demonstration project to provide further evidence on the impact of MTM and other pharmacist interventions that could help promote high quality patient care and lower costs in both the Medicare and Medicaid programs – a win-win for plans, pharmacists, and most importantly, beneficiaries.

There is still more CMS can do to assist pharmacists. CMS continues to engage in rigorous outreach to the pharmacy community, through national, state and local pharmacy organizations and their newsletters and email lists, as well as their standards organization and technical societies. Outreach efforts have also involved hundreds of town hall and state pharmacy association meetings around the country. We have held

numerous national conference calls and posted extensive information on a portion of the CMS website dedicated to pharmacists. Specifically promoting the new pharmacy tools, we produced a CD-ROM that was distributed by all national associations, and held special training events around the country conducted by CMS pharmacists from our ten regions. We will continue our outreach efforts in the coming weeks.

Physician Outreach Provides Information about Formularies, Exceptions, Appeals, and Expedited Requests

Physicians are a key partner in the implementation of the Medicare prescription drug benefit and CMS conducted extensive outreach about formularies, exceptions, appeals, and expedited requests to promote effective interactions with pharmacists and beneficiaries. CMS used the Physicians Regulatory Issues Team (PRIT) website to provide advice for providers and an invitation for them to call or email CMS with issues or concerns about the Medicare prescription drug benefit. We have received and responded to over 200 emails from providers.

In addition, CMS sent a letter to physicians outlining specific sources of help and information including the following.

- A web-based formulary finder linked to all plan formularies.
- Information about Epocrates, an electronic handheld and web-based drug and formulary reference for physicians, that is providing plan formulary information including both tier and step therapy information and is updated constantly.
- An exceptions and appeals contact list for each prescription drug plan so physicians can help a patient by filing a prior authorization for a medication or appeal a medication's tier.
- Information about coverage determinations, exceptions, appeals, and expedited requests.
- A model, faxable form created by a coalition of medical societies and advocacy groups for pharmacists and physicians to use in the event a patient's prescription is not on a formulary or requires an exception request to requirements such as

prior authorization or the level of cost sharing. This optional form provides a straightforward way for the pharmacist to communicate with a physician's office.

- A chart and other support tools to determine quickly if the drug a physician prescribed is a Part B or Part D drug.
- Information about the CMS web-based email and weekly conference calls where physicians can get direct help with their concerns.

CMS Works With States

Since both CMS and the States are responsible for administering benefits for the dual eligible individuals, CMS is committed to working with States on an ongoing and collaborative basis. CMS and the States commenced work in August 2004 through a State Issues Workgroup, which included representatives from State Medicaid Agencies, the Social Security Administration, and CMS to assure that States report and CMS knows of every dual eligible beneficiary in the country undergoing the transition from Medicaid to Medicare drug coverage. In addition CMS and the State workgroup collaborated to:

- develop an efficient and effective application process for low-income beneficiaries who are not dual eligible individuals to apply for assistance with their drug costs;
- train, educate, and conduct outreach in a coordinated fashion;
- develop a process to auto-enroll every full benefit dual eligible beneficiary who does not join a Medicare prescription drug plan on his or her own;
- develop strategies for transitioning dual eligible individuals from Medicaid to Medicare while also assuring coordination of care; and
- assure that the calculation of the phase down State contribution is accurate.

CMS also engaged the States in a series of summits, conference calls, and workshops to discuss and address implementation issues associated with the MMA. These gatherings include monthly all-State conference calls; State Pharmacy Assistance Program (SPAP) Workgroup conference calls; and conferences hosted by organizations representing the States. In addition, CMS provided States with:

- enrollment information for full-benefit dual eligible individuals including their assigned plans,
- comparative information on the specific Medicare prescription drug plans including formularies and pharmacy networks that are serving each state, and
- targeted educational and outreach materials.

Finally, CMS has worked diligently with States to appropriately identify their full benefit dual eligible individuals. CMS validated the information that States reported to minimize reporting errors, mistakes, and omissions that may affect the identification of the States' full benefit dual eligible residents. These validation data matches achieved rates of over 99 percent for all States, according to an independent evaluation completed in the fall of 2005.

Reimbursing States for Assisting in the Transition Process

Despite extensive planning and preparation, some dual eligible beneficiaries, particularly those who switched plans late in a month, have had difficulty obtaining their prescriptions at the pharmacy. Due to these difficulties, 32 States took action to ensure people received the medicines they need by activating their state payment systems. We appreciate the States that supported pharmacists who have faced difficulties in serving certain dual eligible beneficiaries. States are paying for prescriptions that should be paid by the new Medicare prescription drug plans, and CMS believes they should be reimbursed for these expenses.

To that end, we have established a demonstration project to reimburse States for costs they incur by covering drugs that should be covered by the appropriate plan. Under the demonstration, Medicare will reimburse States by reconciling drug payments with prescription drug plans, and by paying any differential between the drug plan reimbursement and Medicaid costs, as well as certain state administrative costs. As of February 16, 2006, forty-five States and the District of Columbia have been accepted into the demonstration program. Of the States accepted into the demonstration program,

about 15 did not activate their state payment systems and are seeking reimbursement only for administrative costs.

CMS is asking States to implement steps to help assure that pharmacists have: checked enrollment status through a card, plan letter, or eligibility query; attempted to contact the plan or the Medicare line in case of incorrect copayments or coverage information (where phone wait times are reasonable); and, in the presence of evidence of Medicaid eligibility, billed through WellPoint. States that work with CMS to implement best practices like these to support pharmacists in using the new Medicare systems have already limited billing to their state systems, often to just a very small fraction of dual eligible beneficiaries and most States do not need to use their billing system at all. In New York, for example, claims fell from over 40,000 paid claims a day during the third week of January to less than 4,000 paid claims per day since February 16 after one modification in the system was made to ensure claims were processed in accordance with the interim billing instructions, which help assure that the Medicare drug plan is billed first. While daily payments to the pharmacists dropped to only a small fraction of total drug expenditures, CMS cannot draw firm conclusions until pharmacists have additional time to use the system.

Of those States that are using their payment systems and have implemented steps like these, most have had only limited drug claims. For example, Florida has had fewer than 100 claims billed to its system and Pennsylvania has incurred fewer than ten thousand claims over the past two months. In these States, the State claims account for well under one percent and three percent, respectively, of the prescriptions for dual eligible beneficiaries.

Among the small number of States that have the highest rates of claims billed to their state systems, most are including drug claims billed for other beneficiaries. For example, New Jersey, Connecticut, Maine and Vermont included claims for beneficiaries enrolled in state pharmacy assistance programs only some of whom are included as eligible in CMS' instructions to States for participation in the demonstration.

Upon receipt of appropriate and correct claims data from a state, we plan to provide estimated payments within four weeks. CMS recently contracted with Public Consulting Group to coordinate claims processing, payment and reconciliation between the States and the Medicare prescription drug plans.

On February 23, CMS extended the demonstration through March 8, 2006. If States are following our guidelines and acting as a payer of last resort, we will consider granting further limited extensions to the demonstration as necessary. At this time, States do not need to file separate extension applications. We are in weekly, if not daily communication, with the States and monitoring metrics such as claims volume.

Monitoring Plan Compliance with CMS Requirements

It is important to note that the plans providing drug coverage to people with Medicare are under contract with CMS. We are enforcing compliance with plan contracts, including call center responsiveness (as discussed above under customer service), formulary requirements, appeals processes, and pharmacy contracting. We are addressing issues on a case-by-case basis. While we are responding to complaints, we are also monitoring trends. This tracking information can lead to corrective action or sanctions if needed, and will be considered in our contracting decisions for future years. While most plans are complying with the requirements set forth in their contracts, we will use the full array of administrative tools and other enforcement remedies to ensure plans adhere to the terms of their contracts. When we hear of specific complaints we work with plans to ensure timely resolution.

Extensive Plan Formulary Requirements Provide Access to Needed Prescription Drugs

CMS developed a set of checks and oversight activities to ensure that prescription drug plans offer a comprehensive benefit that reflects best practices in the pharmacy industry, as well as current treatment standards. Plan formularies must recognize the special needs of particular types of people with Medicare, such as individuals with mental health issues, individuals with HIV/AIDS, individuals living in nursing homes, people with

disabilities, and others who are stabilized on certain drug regimens. CMS reviewed plan formularies and benefit structures to verify that they are in compliance with the following critical requirements. A plan's formulary must cover multiple drugs in each class with a minimum statutory requirement of at least two drugs in each approved category and class (unless only one drug is available for a particular category or class). Furthermore, CMS requires that each plan's formulary include all or substantially all drugs in each of the following key categories: antidepressants, antipsychotics, anticonvulsants, anticancer drugs, immunosuppressants, and antiretrovirals for treating HIV/AIDS.

In addition, each Medicare prescription drug plan's formulary was developed and reviewed by the plan's pharmacy and therapeutics committee. Each formulary must be consistent with widely used industry best practices. Furthermore, CMS compared the prescription drug plans' use of benefit management tools to the way these tools are used in existing drug plans to ensure they are being applied in a clinically appropriate fashion. Prescription drug plan formularies typically include upwards of 80 percent of the 100 most commonly used drugs.

In the long-term care setting, most Medicare prescription drug plan formularies are in general more robust than State preferred drug lists or commercial formularies. Plans must accommodate within a single formulary structure the needs of long-term care residents by providing coverage for all medically necessary medications at all levels of care. Coverage of all medically necessary medications may include, but is not limited to, alternative dosage forms such as liquids that can be administered through feeding tubes, intravenous medications, or intramuscular injections.

CMS will review any request for deletion of a drug from a plan's formulary to ensure continued access to a broad range of drugs. Plans cannot remove a drug from their formulary without, among a number of other steps, first obtaining CMS approval and providing a 60-day notice to their enrollees.

In addition, CMS developed specific procedures for timely exceptions and appeals to ensure that enrollees receive prompt decisions regarding whether medications are medically necessary. Using those procedures, a Medicare beneficiary can get coverage for a drug that is not on a plan's established formulary. For example, if the enrollee is requesting coverage of a non-formulary drug, the drug may be covered if the prescribing physician determines that all of the drugs on the formulary would not be as effective as the non-formulary drug or would have adverse effects for the enrollee, or both. The plan would have to review the physician's determination and must make its decision as expeditiously as the enrollee's health condition requires after it receives the request, but no later than 24 hours for an expedited coverage determination or 72 hours for a standard coverage determination. We are collecting information on the use of a plan's appeals and grievance processes.

Ensuring Pharmacists Receive Prompt and Accurate Payments from Plans

We have heard from pharmacies about the early problems they faced in receiving payments from the prescription drug plans for the services they provided. While new billing and payment cycles caused cash flow issues at some pharmacies in January, pharmacies now are receiving payments in regular cycles in accordance with their plan contracts. CMS is taking compliance with required contractual payments very seriously, and we are monitoring plans to ensure they are abiding by their contracts. Our investigations to date have found that pharmacists are generally being paid according to their contracts, though some are having other difficulties, such as not connecting the name of the payer with the prescription drug plan or facing challenges in matching claim dates with payment dates making it difficult to reconcile books. CMS will continue to investigate and track any complaints from pharmacists regarding payments.

Anticipating Next Steps

In addition to the actions CMS took to address issues that arose at the start of the new Medicare prescription drug benefit, we are looking ahead to ensure we address any issues facing people with Medicare, caregivers, providers, the plans, and pharmacists in the future. For example, we continue to take steps to address and respond to cases where

beneficiaries join or switch plans late in the month and seek to use their coverage soon after. We are also anticipating increased enrollments ahead of the end of the open enrollment period in May, and we are continuing to optimize systems to limit problems with coverage at the pharmacy counter on June 1.

CMS is continuing to work with the prescription drug plans to assure accurate and up-to-date information on all their dual eligible beneficiaries through additional file checking and more frequent data exchanges. We will continue to improve data translation among Medicare, the health plans, and States to continue reductions in the number of rejected or delayed transactions. CMS also is monitoring plans' customer service and hotline wait times, while also providing responsive service through 1-800-MEDICARE. Aggressive outreach, education, and monitoring efforts are continuing, with particular focus on the transitional coverage for a beneficiary's current drugs. CMS continues to work with the States participating in the reimbursement program to assure effective use of Medicare coverage by connecting beneficiaries to their new Medicare prescription drug plans and helping pharmacists use Medicare backup systems if necessary. As implementation continues, and more and more beneficiaries select and enroll in a new prescription drug plan, CMS will continue to improve the program and problem solve, guided by the lessons we have learned to date.

Conclusion

Thank you for the opportunity to discuss our progress during the first two months of the Medicare prescription drug benefit. While we are pleased that millions of Medicare prescriptions are being filled every day, we are going to continue working to ensure every person with Medicare can use their coverage smoothly. I am happy to answer any questions you may have.

MR. DEAL. Thank you. Let me, first of all, start with the New York Times article that was alluded to by Mr. Dingell and several of us have seen, and that is with regard to people who may have been enrolled in

two plans and whether or not they are going to be charged the premiums out of their Social Security for two plans. What precautions have you taken and what are your plans to be able to unravel that particular problem?

DR. MCCLELLAN. Mr. Chairman, in the first two months of the program, about 800,000 people with Medicare have switched plans in an effort to get into the plan that best meets their needs. The vast majority of these people are dual eligible beneficiaries with Medicare and Medicaid. A large number of these beneficiaries are using their new plan effectively, but some of them do have coverage that is active from both plans. We have been careful about turning off the payments from the old plan, the original plan, because we want to make sure that these beneficiaries get the drugs that they need at the pharmacy.

Sometimes these switches have been done by States acting on behalf of their beneficiaries and the beneficiaries may not know about it. The switches may occur late in the month and a beneficiary might show up at the pharmacy early in the next month and the information may not have fully caught up, so we want to make sure that the beneficiary does have coverage when they go to the pharmacy and we are conducting reconciliation between these plans in order to make sure that the payments work out appropriately.

We are encouraging beneficiaries to enroll earlier in the month, as I just said, to prevent this kind of problem from happening and when they do, they will be able to use their new plan smoothly. Now, because the vast majority of the people who are in this situation are dual eligible beneficiaries, they don't have any Medicare premium to pay, so they are not going to be billed by Social Security for any double premium. They won't be billed for any premium at all. To make sure that the information on eligibility for extra help goes to the new plan, as well as the old plan, in a timely way, so beneficiaries are charged the right co-payment, we not only send out this information when the enrollment comes in from the new plan, we also have sent out a number of special files that the plans can use to make sure their co-payment information is up to date. As a result of these kinds of steps, we have seen far fewer cases of problems with co-pays for these individuals or a problem with premiums and the like.

So we have seen a large number of people switch plans. For many of them, the new plan is the plan that is active and is working just fine. We want to make sure that nobody leaves the pharmacy without their prescription and so we are reconciling the payments for these plans and we will finish working on these issues in the next few weeks.

MR. DEAL. One of the concerns that you heard voiced by several of the panel already is, and I think it is a misconception, and that is the

ability of a plan to change its pharmaceutical list of covered pharmaceuticals. You and I have had a conversation about that. Would you walk through the process whereby if a plan wants to change their formulary, what they would have to do and would you also talk about why that might be a very good thing to have happen?

DR. MCCLELLAN. Sure. As a background, we review the formularies that plans start with to make sure that they meet the requirement that beneficiaries are going to be able to get access to the drugs they need. The formularies used by the Medicare drug plans are broader than the VA formulary and broader than many Medicaid preferred drug lists to make sure that people can get access to the medicines that they need. In order to change a drug on a formulary, the plan must first go through what is called a P&T Committee; this is a committee of experts that review, including independent experts, that review whether the change in the formulary is medically appropriate, and that happens before it even gets to us.

When it comes to us, we go through the same kind of process that happens when we approve the formulary in the first place and make sure that the drug coverage is broad, and that people will be able to get access to medically necessary treatments. Even after we give our approval, the plan must go through a period of notifying beneficiaries with at least a 60 day advance notice, before it takes effect. Now, with all these kinds of steps, it probably won't surprise you to hear that we have had no requests from plans to change their formularies since the drug benefit formularies were announced last fall.

MR. DEAL. We are going to hear from the representative that Representative Allen alluded to from his State of Maine in the next panel with regard to problems that they may have encountered. Is Maine one of those States that is a model State for purposes of the plan you previously alluded to and is Maine one of those States that waited toward the very end of the year to make a transfer of their dual eligibles and if so, was that part of the problem there?

DR. MCCLELLAN. Well, we have been trying to work very hard with the State of Maine and other States that have been at the higher end of using their State systems. Like I said before, the vast majority of States either aren't using any State billing at all, or they are using it for only a very limited number of claims, including fewer than a hundred for the whole State of Florida, and a few thousand for the State of Pennsylvania for all of their low-income beneficiaries. Now, Maine did switch some people in plans late in December and there are still some issues with the data coming in from Maine. For example, we have heard from a number of nursing home chains and others that they are not getting the right information on beneficiary location for their dual eligibles. There is a

different co-pay for beneficiaries who are in nursing homes. They don't pay any co-pay at all and we will rely primarily on information from the State for where those dual eligible beneficiaries are located.

We are going to keep working closely with the State and you will hear from the State later today. They are working very hard on this with us. I can tell you that the number of claims that Maine is submitting to us through their State system has gone way down from what they were in January and we have sent some special data teams to Maine to help work out these issues, as well, and we are going to keep working closely with them until they get resolved.

MR. DEAL. Ms. DeGette.

MS. DEGETTE. Mr. Chairman, I will defer to one of my colleagues. I need a minute to get ready.

MR. DEAL. Ms. Capps will be next.

MS. CAPPS. I thank you, Mr. Chairman. Dr. McClellan, again, thank you. I want to touch briefly on a lot of topics, but I want to tell you about a young man who is a constituent who is being treated by a specialist at UCLA for a specific condition requiring him to take Prevacid four times a day. When he was covered by Medicaid, he received this dosage prescribed by his doctor. Now he is enrolled in a Part D plan and only approved for 60 tablets per month, which is only half the dosage his doctor prescribed. The doctor prescribed a certain amount for his need. I have always been concerned that insurance companies practice medicine and dictate the amount of medicine covered. Now, though, it seems that this practice, through Medicare and Medicaid, is being extended to our most vulnerable, often weakest and sickest patient. I am concerned that the patients have to go through such an arduous appeal process and I am wondering what you are doing, very briefly, to ensure that insurance plans provide immediate coverage, not only for the type of medicine but also for the quantity and the way that it is prescribed by the physician?

DR. MCCLELLAN. Well, many plans do have limits on the number of prescriptions, or the dose, or the number of pills provided.

MS. CAPPS. Contrary to the doctor?

DR. MCCLELLAN. Well, in some cases this is for safety reasons and the like, but there needs to be a fast appeals process for resolving that. MediCal does this. I actually prescribed under MediCal, as you know.

MS. CAPPS. I know, yes.

DR. MCCLELLAN. And I filled out a lot of prior authorization requests for increasing doses beyond the usual approved amount. Every plan in Medicare must have a fast process for resolving that issue with the physician. If it is an urgent issue, the plan needs to get back to the physician.

MS. CAPPS. You are working on a faster plan, then? Am I hearing you say that?

DR. MCCLELLAN. Well, if it is an urgent issue, the plan needs to get back to the physician within 24 hours. If the plan doesn't resolve it promptly, it is an appeal that gets handled independently by a Medicare reviewer and if it hasn't happened in this case, that is exactly what our complaint lines and assistance--

MS. CAPPS. But it is taking a long time.

DR. MCCLELLAN. Well, it shouldn't take long and I hope you will send me the specific information on that case.

MS. CAPPS. I will send you the specific information, but I want to move on. I listened to your response to Mr. Deal and because I have been really concerned about fairness. Insurance companies can switch around, and patients have to go through this arduous process. Even though you answered him and I still believe that there are ways that insurance companies, through the different tier levels and also because they don't even have to notify a patient that they have changed, and they can just post it on the web site. You know a lot of these seniors do not have access to web sites, so I just want to register that, but I want to move on because I have two more questions to ask you.

One has to do with proposals in Congress to extend the enrollment deadline past May 15. Maybe this, because they are all coming from the minority side, just has to be rejected out of hand, but I am imploring you to see if there is some way that we can get the Administration to acknowledge that we need to delay the deadline of May 15. I am afraid we are going to hear--I mean, we heard loud and clear on January 1st and the few days after that, but now we are going to find out that very vocal Medicare recipients are going to run into that deadline and still be as confused as they are telling me today.

So that is one question, but I want to ask another one right away, but get an answer to both of these. There is certain evidence that some plans are providing incentives to sales agents and encouraging employees to entice beneficiaries into signing up for HMOs instead of just the prescription plans. There is a reason the insurance companies haven't switched their plans yet, because they are still sweetening, they are trying to enroll beneficiaries, so they are going to make it really nice for them. I am sorry if I sound cynical about this, but I want to know what steps you are taking to protect beneficiaries who are elderly and/or disabled from being lured into HMOs when the stand-alone prescription benefit would actually be best--and you have acknowledged that this is still one of their choices. It may be the best and the most affordable coverage for them.

DR. MCCLELLAN. Oh, absolutely. Stand-alone prescription plans are available everywhere.

MS. CAPPS. But they are being enticed and baited into joining up with HMOs and they are going to be left high and dry.

DR. MCCLELLAN. Well, the insurance agents are subject to two kinds of oversight. First of all, they are overseen by every State. Every State has a process, since this is a professional agent for licensing and for oversight of their practices and second, Medicare has its own oversight of agents that are involved in selling Medicare policies to make sure that information is presented objectively and that beneficiaries are not given, or that agents are not giving inappropriate financial incentives this year and we would be happy to share the details of that.

MS. CAPPS. Can I get some evidence of this so I can use it on your behalf in fairness to my beneficiaries?

DR. MCCLELLAN. Absolutely. And again, if we hear about any complaints, we will take action. We have sanctioned several plans for marketing violations, not particularly—

[The information follows:]

CMS takes its responsibilities for monitoring and enforcing plan compliance with Part D program requirements very seriously. Our aggressive oversight of prescription drug plan sponsors has resulted in well over a thousand compliance actions this year. Specific examples of compliance activities in the marketing area since last year relate to agent misrepresentations or other misconduct, marketing prior to October 1, 2005, use of unapproved marketing materials, and enrollment systems failures.

CMS uses the full range of available enforcement tools in pursuing plan compliance with Medicare program requirements. This includes issuing numerous corrective action plans and compliance warning letters. Usually, these steps lead to prompt, responsive actions by plans. However, where necessary to achieve compliance, CMS will levy civil monetary penalties and implement intermediate sanctions such as freezing marketing and enrollment. Where necessary, we will also terminate plans. CMS' compliance and enforcement program emphasizes analysis of complaints and plan-reported data, along with routine and focused program compliance audits. We are structuring the audits in a way that ensures independence and unbiased objectivity. We have and will continue to consider information on plan performance annually as we make contracting decisions for future years – including decisions on 2007 contracts.

MS. CAPPS. I just want to get a final yes or no answer to my question. Will you extend the deadline?

DR. MCCLELLAN. We are focused right now on giving everybody help with signing up. The wait times are down now, under a minute for people who call 1-800-MEDICARE. We are helping--

MS. CAPPS. There are millions of people who haven't signed up.

DR. MCCLELLAN. And as you have seen the savings are even larger than expected, hundreds of thousands of seniors are signing up every week.

MS. CAPPS. So you are not committing to extending it?

DR. MCCLELLAN. That is what we are focused on right now. I have heard from not only Minority members, but Majority members who are widely concerned that every senior should have an opportunity to sign up and that is why we are working so hard right now making sure that every senior does, so let us keep talking.

MS. CAPPS. Thank you.

MR. DEAL. Mr. Bilirakis.

MR. BILIRAKIS. Mr. Chairman, I am really pleased to hear Ms. Capps go into details here on problems now or potential problems or whatever because that is what we should be doing. We should be focusing really on that rather then the partisan rhetoric that we hear sometimes during the opening statements. I would not endorse her question, necessarily, but her point that there be a need for an extension and if it looks like that is going to be the case, I will tell you, I will be one of the first people who will be insisting that we do have an extension there because again, our goal is to give everybody an opportunity to enroll. We all admit there are complexities here and things of that nature that may result in some people not being able to enroll in time, so hopefully, Mark, we all have an open mind. We have asked them to have an open mind, we should also have an open mind on some of these things, particularly that area.

I would ask you, sir, step by step; I am an 83 year old beneficiary, I am either computer illiterate or don't have access to one. Take me through the process. I have decided, in spite of what I might read in the newspapers and whatnot, I have read the AARP magazines or whatever the case might be or my neighbors have told me hey, I should enroll so I decided to enroll. Step by step.

DR. MCCLELLAN. Well, I have actually talked to a lot of seniors in that situation down in Florida where we have a lot of organizations working with us to help make sure people like the 83 year old man that you mentioned can get their questions answered and can sign up for a plan. There are lots of ways to get help. One is by calling 1-800-MEDICARE, another is by looking for the events that are taking place on an ongoing basis. We have had several thousand since the year began already, on an ongoing basis, in your district and in his community to find out more about this program. We also partner with the Florida State Health Insurance Assistance Program that can provide--

MR. BILIRAKIS. Well, forgive me. And they can go to some of the pharmacists and they help them and I know some of the physicians help, but let us say they passed that point and they decided they want to enroll.

DR. MCCLELLAN. Okay.

MR. BILIRAKIS. What do they do?

DR. MCCLELLAN. All right, they can call 1-800-MEDICARE and we will walk through enrollment with them on the phone and take them--

MR. BILIRAKIS. Okay, so that is enrollment.

DR. MCCLELLAN. That is right.

MR. BILIRAKIS. Okay.

DR. MCCLELLAN. If they still want help--

MR. BILIRAKIS. Is that the only method of enrollment?

DR. MCCLELLAN. No, there are paper applications, as well, that you can fill out. You can call the plans directly. You can work through one of these many partner organizations. The enrollment form, itself, is just a page, front and back, it takes us a matter of minutes to fill out.

MR. BILIRAKIS. Okay, so now they are enrolled and they have already chosen the plan. When they have enrolled, it shows in the plan, which can be a problem, too. I mentioned in my opening statement about sitting in with pharmacists and I know some of them are, I guess, I don't know whether they are mandated but they are certainly encouraged by their employers, by the company to be very helpful.

DR. MCCLELLAN. Yes.

MR. BILIRAKIS. Now, what is the history there? Are we finding that most pharmacists are educated well enough to be able to do this and are willing to do it? How do we stand as far as that is concerned?

DR. MCCLELLAN. I think the most important thing is that we have seen pharmacists all over the country demonstrate the professionalism of their work and their devotion, really, to helping patients get the medications they need. Independent pharmacists, chain pharmacists, they have all been working very hard to help people take advantage of the program and when there were, especially early in January, these enrollment problems, where the data were not available that they needed--

MR. BILIRAKIS. Okay, they admit they had problems in January?

DR. MCCLELLAN. Yes. They solved those problems themselves. It is a tremendous effort. Now, many of those pharmacists are benefiting from the fact that the wait times have come way down. If a pharmacist calls our toll free help line for pharmacists, they have no waiting at all. The plan wait times are generally now in the five minute range; many plans, lower than that. That is all very important progress, but it is still a lot of work for pharmacists. You are going to hear from some later who have some very good ideas about how this process can be improved even further, steps like getting more standard messages back from the different drug plans when a prescription is not approved so they will know exactly what to do; they won't have to look it up in a manual. Steps like getting more standardized forms for--

MR. BILIRAKIS. That is needed greatly.

DR. MCCLELLAN. That is right. And so those steps are coming, as well. Many pharmacists spent a lot of time in preparation, but especially for the independent pharmacists, they have limited resources, they are very busy running essentially a family business and they have a lot of things going on at the same time, so we have also worked through their associations, through their software vendors, through the different--through the wholesalers. Representative Buyer mentioned earlier about the need to get the payment timing matched up now with this new system, to help provide some additional relief for the burdens that they are facing now. I think there is more that we can do there. We have seen a lot of progress in just eight weeks in the program, but there are more steps that we can take and I truly appreciate the constructive ideas and support from pharmacists in helping us.

MR. BILIRAKIS. And I agree with you. Thank God for them and they have said the same thing to me, that January was a really horrendous month but things have really smoothed out and of course, there is the reimbursement, what they are compensated, a dollar and something per, what is it, per prescription?

DR. MCCLELLAN. We want to make sure that the reimbursements happen according to the contract schedule, so any pharmacists who are not being paid according to their contracts, we want to hear about it. We will investigate those further and make sure the plans are living up to their--

MR. BILIRAKIS. Thank you for all your work, Doctor.

MR. DEAL. Ms. DeGette.

MS. DEGETTE. Thank you, Mr. Chairman. Mr. Chairman, in the absence of the committee Chairman, I just want to say that several of the Majority members said in their opening statements the Democrats wanted this program to fail and all we were was critical of it and in truth, while all of us voted against the bill in the first place, it passed and we felt like we had a duty to our constituents to tell them they needed to enroll in this program, if, in fact, when it passed. So for people like me, I sent a mailing out to my seniors, Ms. Capps is nodding. She did it, too. We sent mailings out telling them how to enroll. We had town hall meetings and forums. We did everything we could and are continuing to do everything we can even though we think it is a bad program. We don't think it is going to work too well.

We think that our constituents should sign up and I think the record should reflect that because we all are really trying to make it work, but what frustrates us is that many people seem to be denying that there are some pretty massive problems with this program and Dr. McClellan, I know that you agree that there are some issues that need to be resolved still, so that is kind of what I want to explore with you this afternoon.

I was heartened to hear Chairman Barton say that in his State, or in his district, people seem to be signing up for this program because in Colorado, my home State, we have over 529,000 Medicare beneficiaries; 353,000 of them have drug coverage, but only 46,000 beneficiaries have actually signed up for the stand-alone PDP and the rest are either in Medicare Advantage, they are dual eligible and so they are automatically enrolled or they have retiree drug coverage through their former employer, so that leaves about 176,000 beneficiaries in Colorado who have yet to sign up for the plan. So my question is how are we going to get these--and I know this is not unique to Colorado. I don't think we are the worse State on this. My question is how are we going to get these remaining 80 percent of people who haven't signed up for a stand-alone PDP to do so by May 15th?

DR. MCCLELLAN. Well, Congresswoman, as you know, about two-thirds of the beneficiaries in Colorado are getting coverage now and thousands more signed up in the last four weeks alone. There are events that are taking place--

MS. DEGETTE. Right, 46,000 have signed up and that is out of 529,000 Medicare beneficiaries. Now, some of them have Medicare Advantage, as I said. Some have private coverage, so are we just not worrying about getting them enrolled?

DR. MCCLELLAN. All those beneficiaries are very important to us. Close to 300,000 of the beneficiaries in Colorado have coverage now. Many are getting--

MS. DEGETTE. But not though this Part D program.

DR. MCCLELLAN. Well, but they don't all need to get it through stand-alone plans. Medicare Advantage plans are more widely available than ever before and we have had half a million people sign up for Medicare Advantage plans just in the last four weeks. And in the last four weeks alone, we saw thousands of people enroll in stand-alone prescription drug plans, as well, so people in Colorado are finding out about this program. I think that there are a lot of ways that we can keep working together to help make sure even more can take advantage of it. We have partners working with--

MS. DEGETTE. So let me ask you this. What I am hearing you say, then, is if people are in other programs aside from the stand-alone PDP, you are not really worried about them, right?

DR. MCCLELLAN. I am worried about making sure that everyone gets the support they need to make a decision about this coverage.

MS. DEGETTE. Okay, that is going to be 176,000 in Colorado alone. By May 15th, how is that going to happen?

DR. MCCLELLAN. Well, a lot of those beneficiaries already have coverage from the VA or they are already getting coverage from

elsewhere and don't want to sign up. Many people may go ahead and make an enrollment decision and those are the ones, the people who--

MS. DEGETTE. How many is that?

DR. MCCLELLAN. It could be--

MS. DEGETTE. You don't know. I mean, you can't say off the top of your head.

DR. MCCLELLAN. Well, I can't say off the top of my head because many people in Colorado get covered through the VA or they have another source of coverage already.

MS. DEGETTE. So you are just not going to worry about getting them enrolled.

DR. MCCLELLAN. I am absolutely worried about getting them enrolled and that is why we are--

MS. DEGETTE. Well, how are we going to do it? It is 80 percent of the people and I understand some of them have other coverage, but starting May 15, they are going to start to be penalized if they, 1 percent, and it compounds if they don't enroll in it.

DR. MCCLELLAN. That is why we want them to hear about this program now and know that there are lots of places they can go for help if they have questions about enrollment. They can call 1-800-MEDICARE--

MS. DEGETTE. Okay, with all due respect, they have heard about it. They have heard about it from me. They have heard about it from TV. They are confused or they are mad or they are whatever and they are not signing up, so why is the Administration so dead set on enforcing this May 15th deadline which is, it is going to affect all these people who have coverage other places.

DR. MCCLELLAN. Congresswoman, what I was just trying to answer is the places that they can go right now to get their questions answered. You said they have questions, you said they want to get more information. What I hope we can focus on is the places that they can go and the resources available to them to get their questions answered, like calling 1-800-MEDICARE or--

MS. DEGETTE. Okay, can I say something? As far back as last fall, they have known that and May 15th is coming up and they are not doing it for whatever reason.

DR. MCCLELLAN. Well, I am not sure all of them do know that. We have been trying very hard to make sure people know where they can call and I appreciate your help in town hall meetings and the like to get the word out. Many people, though, seem to be getting the wrong impression that this is a benefit that is only for people in HMOs. That is not the case and I want to make sure we are getting the facts out with you.

MS. DEGETTE. Okay. So you think you can get everybody enrolled by May 15th?

DR. MCCLELLAN. I want to do all we can to help.

MS. DEGETTE. Yes or no. Can you get them all enrolled by May 15th?

DR. MCCLELLAN. This is a voluntary program. Not everybody may choose to enroll in the program.

MS. DEGETTE. Okay.

DR. MCCLELLAN. What we want to do by May 15th is make sure that everyone has an opportunity to find out and to make a decision about the coverage because they can save a lot of money and get--

MS. DEGETTE. Okay. You don't need to sell the program to me. I know a little bit about it.

DR. MCCLELLAN. I know you do.

MS. DEGETTE. But let me ask you another question. For these dual eligibles, the low-income Part D folks, a lot of those people have applied and they are waiting for their applications to be approved before they sign up for a plan because in large part, they can't afford to do it without a subsidy. Now, SSA's deadline for processing the applications extends beyond the May 15th deadline for beneficiaries to sign up for a plan without a penalty. So my last question to you is if a low-income Medicare beneficiary doesn't hear about their subsidy until after May 15th, then they are going to incur a 1 percent penalty for the rest of their lives for not signing up earlier. Has your agency considered doing something about those people because there are two separate deadlines and one is later than the other?

DR. MCCLELLAN. That is a very good point. We have been working with Social Security on ways to get their processing time down, the time to get this information in the system, so I would like to talk with you further about additional--

MS. DEGETTE. Okay, would you be willing to consider, for those folks, extending the deadline for the penalty past May 15th?

DR. MCCLELLAN. For people who are low-income, who have tried to--

MS. DEGETTE. Who have applied.

DR. MCCLELLAN. --get enrolled in the program, who have applied, if you want to--

MS. DEGETTE. And they have not heard--

DR. MCCLELLAN. Absolutely. We want to find a way for them to take advantage of the program and I would be delighted to--

MS. DEGETTE. And so would you be willing to consider extending past May 15th for that group of people the, for waiving the penalty. Would you be willing to consider that, yes or no?

DR. MCCLELLAN. I am willing to consider the best--

MS. DEGETTE. Thank you.

DR. MCCLELLAN. --approaches to make sure they can take advantage of the benefit.

MS. DEGETTE. Thank you.

MR. DEAL. Mr. Buyer is recognized for questions.

MR. BUYER. Dr. McClellan, I have great respect for the job that you have in front of you. What I would like for you to know that those who ride the unicorn and dream are not just individuals in our own society that have some socialist view. Let us go to a socialist country for a second, okay? Let us go to one, okay. So let us go to their dreamland for a moment. Oh, this is a wonderful newspaper here, right? The International Express, United Kingdom. Look at this. "The cancer drugs ruling scandal." The courts made a ruling. Now, those of who even ride the unicorn in a socialist system are upset in Great Britain. Why? Let us figure out why.

See, the ruling condemns women to death in the United Kingdom. What is this about? So the courts rule that the national health system primary care trust, they couldn't force the trust to give Herceptin to women with breast cancer. So here we have this whole situation again. You have a blockbuster drug. People, not only in America, but around the world have this expectancy of a right to a drug at a cost for which they are only willing to pay. Wow. That is this fantasy world out there that somehow--how are we ever going to be able to achieve these great blockbuster drugs that can save human life, Doc?

So I just want to let you know that the challenge for which you are facing, okay, is by the riders of the unicorn that are not only in America, but they are also all over the world, okay? I just found this rather intriguing, so it is not just you, okay? So those who ride the unicorn, I guess, have this expectancy and right that everybody ought to be able to get a drug, equal basis for free, are the same belief that everybody ought to drive the same type of automobile. That is why earlier I said the dead horse is the command economy. It was in Russia and it failed.

Let me ask this question. Earlier on in my opening comments, I asked you about this difference between the word that you used in your national letter about requested versus required, so this will go to your authorities. So trying to make sure that the plans are responsive to the pharmacists, tell me what you perceive your authorities are with regard to these plans.

DR. MCCLELLAN. We have extensive authorities to make sure that the plans fulfill their contractual obligations to provide timely access to drugs and timely reimbursement according to contracts with the pharmacies. That authority has been used to take steps like making sure

that the transition period was extended in order to accommodate the fact that many beneficiaries couldn't get through to their plans early in January and that not enough steps had been taken to successfully implement prior authorization appropriately and effectively for all beneficiaries.

It is authority that we are using to make sure that if a pharmacist has a complaint about how they are being paid, about whether their payments are being made according to contractual schedule, that we can look into that, and if we see patterns of abuse that the plans don't respond to quickly, we can take further actions. We have a range of further actions we can take when necessary that goes all the way up to suspending enrollment in the plan or eliminating it from the prescription drug program.

MR. BUYER. With regard to individuals who are communicating directly with the pharmacist, one of the concerns has been will the message or the answer be consistent? You know, all these pharmacists, they all know each other. They are all trying to work through it, too. So my question is are you working on a standardization of the communication?

DR. MCCLELLAN. We are and we have seen a lot of leadership in making that happen from the pharmacy community. Some of the representatives of the independent pharmacists and the chain pharmacies are working with the drug plans to come up with what those standards should be and we have already seen some early benefits of that work. For example, this past week this collaboration of plans working with pharmacies and other groups sent a letter to the standard setting organization to request that standards be added in certain areas where plans have been getting different kinds of messages back. Now, I think we are going to see more of that in the weeks ahead.

MR. BUYER. Would you address the concern I raised earlier about what I title economic defibulation? How we are actually going to be able to put all this on a proper cycle to give everybody back--

DR. MCCLELLAN. That is a good question. We have already had some discussions with wholesalers and distributors who have made adjustments in many cases in their payment schedules to accommodate some of the payment issues, especially back in January when there was this gap between when the Medicaid payments and the cash payments stopped and the drug plan payments started. I think pursuing that to make sure that the payment systems work as smoothly as possible for pharmacists--

MR. BUYER. We want to work with you. Thank you.

DR. MCCLELLAN. We will do that.

MR. DEAL. Mr. Dingell is recognized for questions.

MR. DINGELL. Mr. Chairman, I will be submitting a letter to the witness requesting answers to a series of rather complicated questions for which there is not time at this moment. I ask unanimous consent that the record remain open and that I be permitted to insert the same into the record?

MR. DEAL. Without objection.

MR. DINGELL. Thank you, Mr. Chairman. Witness, these question are--I have tried to craft them in a way that if you would choose to answer yes or no because of the difficulty that we confront in dealing with the complexity of this question. So if you can, yes or no. Isn't it true that CMS does not know how many of the top 100 drugs used by seniors are subject to prior authorization across all stand-alone Part D plans?

DR. MCCLELLAN. Well, yes. The plans have told us--

MR. DINGELL. Thank you. Now, let me proceed, if you please. Isn't it also true that, as you mentioned on page 34, that CMS does not have procedures such as time frames for exceptions and appeals in order to define how the appeals and the requests for relief from the bureaucratic processes of the insurance plan are attended to?

DR. MCCLELLAN. Yes, we do have time frames and--

MR. DINGELL. You do?

DR. MCCLELLAN. We do have time frames for exceptions and appeals and the time frames for urgent exceptions where the beneficiary--

MR. DINGELL. I would appreciate it if you would submit to us a clear statement of what it is that the rights of a citizen are and how you, at HHS, standardize these matters?

DR. MCCLELLAN. Well, we would be glad to do that.

[The information follows:]

INSERT FOR THE RECORD OF THE HON. MARK MCCLELLAN, ADMINISTRATOR, CENTERS FOR MEDICARE & MEDICAID SERVICES

There are five levels of the appeals process that an enrollee may appeal to:

Level		Standard Appeal	Expedited Appeal*
1	Redetermination by Part D Plan	If the Part D plan's initial coverage determination is unfavorable, an enrollee may request a ***redetermination*** and the plan has up to 7 days, to make its decision.	Same as standard except the timeframe is up to 72 hours for the plan to make its decision.
2	Reconsideration	If the Part D plan's redetermination is	Same as standard

	by Independent Review Entity (IRE)	unfavorable, an enrollee may request a ***reconsideration*** by an IRE, which is a CMS contractor that reviews determinations made by a plan. The IRE has up to 7 days, to make its decision.	except the timeframe is up to 72 hours for the IRE to make its decision.
3	Administrative Law Judge (ALJ)	If the IRE's reconsideration is unfavorable, an enrollee may request a hearing with an ALJ if the amount in controversy requirement is satisfied.	Not applicable.
4	Medicare Appeals Council (MAC)	If the ALJ's finding is unfavorable, the enrollee may appeal to the MAC, an entity within the Department of Health and Human Services that reviews ALJ's decisions.	Not applicable.
5	Federal District Court	If the MAC's decision is unfavorable, the enrollee may appeal to a Federal district court, if the amount in controversy requirement is satisfied.	Not applicable.

*An expedited decision is requested based on the urgency of an enrollee's health condition.

CMS and Part D plans will be providing a considerable amount of information to beneficiaries, caregivers, patient advocacy groups, providers, and the general public about coverage determination and appeals processes so that all Medicare beneficiaries receive medically necessary drugs and their continuity of care is preserved. CMS will be monitoring plans and reviewing beneficiary's complaints to ensure that plans do not engage in discriminatory practices. Enforcement actions will be taken against plans that violate Medicare's requirements.

MR. DINGELL. I note, again, yes or no, CMS does not have good data on how many of the drugs in the six protected classes, that is mental health drugs, cancer drugs, et cetera are still subject to prior authorization across plans, yes or no?

DR. MCCLELLAN. For people who are already stabilized on the drugs--

MR. DINGELL. Six protected classes.

DR. MCCLELLAN. They are generally not subject to prior authorization.

MR. DINGELL. They are not?

DR. MCCLELLAN. They are not. If people are already stabilized on a certain drug, they can continue using that drug. For someone who is a new user, the prior authorization procedures do need to be noted by the--

MR. DINGELL. What happens when the beneficiary goes to the pharmacist?

DR. MCCLELLAN. If the beneficiary is already taking drugs that they need for their mental health, for their mental wellness, the beneficiary is

getting covered for those drugs and millions of our beneficiaries are getting that coverage right now.

MR. DINGELL. What protection do you give the beneficiary against unaffordable cost sharing?

DR. MCCLELLAN. Beneficiaries with limited incomes have a tremendous benefit where they are paying only $1 in $3 in cost sharing for their drugs. The beneficiaries--

MR. DINGELL. The answer really is nothing.

DR. MCCLELLAN. I think the answer is that millions of beneficiaries have new coverage that they didn't have before so they can afford the drugs that they couldn't in the past. That is why we are seeing so many more prescriptions being--

MR. DINGELL. Let us hope that the beneficiary has the good eye of the Lord, the good ear of the Lord because I am not sure he will get much help from the agency. Now, let us talk about this. CMS cannot provide me the number of beneficiaries that have been denied or failed to get medicines they were told were on the formulation or rather, on the formulary because of prior authorization procedures. Is that correct or--

DR. MCCLELLAN. We will be reporting on complaints that beneficiaries bring about prior authorization or formularies not being followed. We will be making that information public in the coming weeks. We are just gathering that now. We are only eight weeks into the program and our focus has been on identifying problems and getting them solved individually so that beneficiaries get the medicines they expect.

MR. DINGELL. Let me just ask you a simple question. If you don't know how many people have been denied, how then can you say this plan is working well?

DR. MCCLELLAN. Because we know that millions of prescriptions are being filled and we know that when a beneficiary has a complaint and brings it to us, we work with the plan to solve that complaint.

MR. DINGELL. You are one of the more trusting people that I have had before this committee as a witness. Isn't it true that many Part D plans have higher cost sharing than is usually seen in commercial plans, yes or no?

DR. MCCLELLAN. The drug plans had a benefit design that is less generous than some employer plans. The drug benefits are providing more than 50 percent savings for people with Medicare.

MR. DINGELL. Thank you very much. Now, don't we have a situation where there is no clear way that a complainant or a covered beneficiary can know that he or she has a standard right to appeal from denial or non-coverage on the formulary?

DR. MCCLELLAN. Beneficiaries can get that information from many different sources. They can call 1-800-MEDICARE, you can get from--

MR. DINGELL. What are the rules the Department has to assure that there is such a standard mechanism?

DR. MCCLELLAN. When an appeal comes in to us, it is handled by an independent Medicare reviewer not connected with the plan, who follows a standard set of procedures.

MR. DINGELL. I am not asking you how you handle it, I am asking you what assurance is there that there is a standard mechanism for handling these that can be easily understood by the beneficiary?

DR. MCCLELLAN. Well, that is part of our oversight, which I take very seriously, that we have independent reviewers available if a beneficiary hasn't been able to work out a coverage issue with the plan, they can quickly come to us to get appropriate resolution. It is a very important part of our oversight.

MR. DINGELL. I will be sending you some, I am sure, because I am sure we will shortly be receiving complaints on this matter.

DR. MCCLELLAN. Well, please do.

MR. DINGELL. Mr. Chairman, I thank you. I yield back.

MR. DEAL. Chairman Barton is recognized for questions.

CHAIRMAN BARTON. Thank you, Mr. Chairman. Thank you, Dr. McClellan. Doctor, how many plans are out there for seniors to choose from?

DR. MCCLELLAN. It depends on where they live, but in most regions of the country, there are between about 11 and 20 organizations that are offering prescription drug coverage. Some of them offer a basic plan that is very low cost. In many parts of the country you can get coverage starting at $2 a month and that goes up to a much more comprehensive benefit with no donut hole, no deductible, very comprehensive for the beneficiaries who want that.

CHAIRMAN BARTON. So what would be the least number of plans in any part of the country? In other words, where are there fewer plans? And if you know how many that is it would be great.

DR. MCCLELLAN. I don't have exact numbers off the top of my head, but in Alaska and Hawaii, probably in the range of 30 or so choices.

CHAIRMAN BARTON. Thirty or so choices in Alaska and that would be the fewest?

DR. MCCLELLAN. Yes.

CHAIRMAN BARTON. And in most of the country there were, I have heard, up to 70. Is that a fair estimate?

DR. MCCLELLAN. Probably not that large. Typically, there would be 40 to 50 plan options.

CHAIRMAN BARTON. Forty to 50. Now, to go to Congressman Dingell's question about a drug that is not on the formulary. Why would a person with that many plans choose a plan that didn't cover the drugs they were taking?

DR. MCCLELLAN. Well, one of the options that is available to beneficiaries now, which is a really first ever is if they have a specific set of drugs that they like that they want to be sure is covered, they can find out from us ahead of time not only which plans cover those drugs, but how much they can save on those plans and it is much better, I think, than just having one national formulary where the vast majority of beneficiaries would have no choice but to have to change the drugs that they are taking. You know, they can do that if that is what they want to do, but they have got the option--

CHAIRMAN BARTON. Is it a fair statement with that many options and that many plans that admittedly that it is complicated and it is difficult to sift through all these plans? That is a fair criticism. But with that many choices, there can't be too many people that can't find a plan that covers, if not all the drugs, the overwhelming number of drugs that they actually take on a routine basis.

DR. MCCLELLAN. That is right. Out of the top drugs used by seniors, plans generally cover 70 or 80 or more of the top 100 and there are plans available that cover all 100 of them and not only that, people can get coverage that fits what they want, no deductible; a flat, predictable co-pay, if that is what they want; the kind of coverage they want with the drugs that they want.

CHAIRMAN BARTON. How long do you think it is going to take to get the not just anecdotal stories, but real data about any systemic problems? I mean, it would be a problem if let us say half the seniors chose one plan and that one plan didn't cover two of the most routinely taken drugs. That is a problem.

DR. MCCLELLAN. We are tracking the complaints that we get about plans and those have generally been going down. We had more in early January when, as we have already discussed, there were some data problems, and wait time problems, and people had more trouble getting their prescriptions filled, but we will keep watching closely. So far, we are seeing millions of our beneficiaries getting coverage for the first time, millions more getting much more comprehensive coverage than they have ever had from Medicare and so they are getting those prescriptions that they want filled on the plan that they chose.

CHAIRMAN BARTON. There has been some criticism that these plans can drop drugs from the formulary and I think that is a valid criticism. Is it also true that they can add drugs?

DR. MCCLELLAN. Yes.

CHAIRMAN BARTON. Now, if, in fact, you have a popular plan, that there is consistently a drug or two or a half a dozen that people need and they are not on it, what does the plan sponsor have to do to get it? Do they have to get permission to put these drugs on the formulary or do they just do it? What is the process?

DR. MCCLELLAN. They can just do it and we have seen that happen with new drugs that have been approved by the FDA since the formularies were first submitted by the plans. We have seen no cases of plans dropping drugs that they initially put on their formularies.

CHAIRMAN BARTON. What is the experience, if any, so far in the co-payment price in the monthly premium that people are paying? Are those going down or going up?

DR. MCCLELLAN. Premiums are set. Those are locked in for the year. The out-of-pocket payments that beneficiaries are making are set in many of the plans. That is why I think a lot of people are choosing plans that have a flat co-pay, you know, $3 for a generic drug, $20 for a brand name drug. That is set for the year, as well. The price changes that we have seen have generally only happened on drugs where the price for the drug went up across the board, not in Medicare only, but in public plans like Medicaid and the VA, as well, and we have not seen any disproportionate rises in the Medicare program even in those cases.

CHAIRMAN BARTON. And this is my last question because my time has expired. Is there enough data yet to indicate which plan is turning out, on a national basis, to be most popular? Are you seeing a preponderance of the seniors gravitate to one particular plan or to one group of similar type plans?

DR. MCCLELLAN. Well, if you look at the press releases and the like from the drug plans, there definitely are some plans that are turning out to be more popular than others. What I can tell you is that seniors are generally not choosing the plan that was designed by the Congress, despite everyone's best efforts. They are choosing, instead, plans that have no or little deductible, that have flat co-payments that fill in the donut hole, that have other features that the plans have designed because that is what they thought people would want instead of the standard plan. From that standpoint, the market is giving people better benefits at a lower cost, a much lower cost than people had expected.

CHAIRMAN BARTON. Is that a good thing or a bad thing?

DR. MCCLELLAN. I think it is a very good thing, from what the many seniors that I have talked to around the country have said. You are right, that it does take some effort to find out about the plans and choose a plan that is good for you. But my experience in talking with seniors, which is born out in survey after survey, is that seniors who have been through the process overwhelmingly say it was worth the effort, they are

saving a lot of money, they are getting the kind of coverage that they want, they got to choose a plan and we are seeing that happening for millions of Medicare beneficiaries for the first time ever.

CHAIRMAN BARTON. Thank you, Mr. Chairman. Thank you, Doctor.

MR. DEAL. Mr. Waxman is recognized for questions.

MR. WAXMAN. Thank you very much, Mr. Chairman. Dr. McClellan, I would like to ask you about a disturbing finding about increasing prices under the new Medicare program. In a report released last week by my staff, they compared the prices offered for identical drugs by ten Medicare drug plans in December of 2005 and then February 2006, and the findings were shocking, even to those of us who already had concerns about Medicare plans. In just the first seven weeks of this new Medicare drug program, average prices for ten leading brand name drugs increased by 4 percent. The average price for one drug, the stroke medication Plavix, increased by 11 percent. Are these kinds of increases, price increases what you have in mind when you claim that the competition among the plans is helping to hold down prices?

DR. MCCLELLAN. Absolutely not, Congressman, and that is why we went back and looked at the price changes that your staff reported on and found that the actual increase, if you look across all the Medicare prescription drug plans, matches up with the average increase in AWP, that is the price charged for all payers, whether you are Medicare or Medicaid or the VA, any program, and many of the plans have had smaller increases because they have flat co-pays that don't change at all. So we have seen no significant changes other than what has been due to the increase in the list prices for the drugs that apply to everyone, including the VA programs and other programs. We are watching this very closely.

MR. WAXMAN. Well, this a very short period of time to have a 4 percent increase in the price of these drugs. We are talking about a matter of weeks.

DR. MCCLELLAN. Well, it is a result of the timing that you looked at. Around January 1st is when a lot of drug prices historically have increased. These AWP changes occur on a quarterly or annual basis and the drugs that have the AWP increases were pretty much the drugs that had the increases on January 1st, 2005; January 1st, 2004. I think the good news here for seniors is that they are getting discounts now of 30 percent to 50 percent off the prices of drugs on average and that they are continuing to get those discounts, so if these prices go up, they are still getting big savings compared to what they would pay on their own and/or in any other program.

MR. WAXMAN. Well, with all due respect, I think you are illustrating why CMS has a credibility problem because the facts on the ground are pretty clear and these facts show the drug prices are going up; several analysts have seen it, and as far as the discounts, the first thing I want to mention is that the analysis from my staff has shown that the drug plans aren't providing big discounts at all. The prices are way too high. But more importantly, what my latest report shows is that even if the plans do provide some kind of discounts, they can raise the prices at any time and make these discounts disappear. That is what seems to be happening here. Plans have raised prices over 4 percent in just a few weeks.

DR. MCCLELLAN. Again, if you look across not just the ten, you know, plans that your staff handpicked, but across all the plans, look at the average change in prices. The average change across all the plans is only around 3 percent, which matches up with the numbers in your own report for how AWP has gone up, the price changes that you saw that are occurring in the VA and Medicaid programs and other government run programs, as well.

MR. WAXMAN. Well, let us look at that, because there are other benchmarks. The prices offered by the Medicare plans have gone up far faster through the other benchmarks such as they have gone up faster than the wholesale drug prices, even though you say it is the same as the wholesale price drug price increases. They have gone up faster than drug prices in Canada. They have gone up faster than prices at Drugstore.com. It seems to me that we are finding a big increase and not a decrease that we thought was supposed to be the result of this competition. One of the most disturbing things that my report found was that the plans that posted the lowest prices in December had the biggest price increases in February. This looks like a classic bait and switch; after millions of beneficiaries signed up for the plans, all of a sudden price increases by as much as 10 percent in just seven weeks, can you tell me what CMS is doing to keep plans from pulling these kinds of bait and switch--

DR. MCCLELLAN. Well, we have been tracking the prices since this program began, since the data started being posted in November. By the way, this is the first time we have had this kind of transparency in prescription drug pricing ever and I am glad that your staff is taking advantage of some of that information, but we have been watching it closely since the beginning of the program. Again, the increase that we have seen, I had a long letter to Consumers Union about this--they had some concerns and it is appropriate for everybody to be watching this very closely--where we went through in detail the price changes they had seen and showed that it was due to two things; one is where the AWP for

the drug changed, which applies to everyone, whether you are in Medicare or in the VA or any other program.

MR. WAXMAN. I know that is your argument.

DR. MCCLELLAN. And number two, to some specific data problems from week to week and what certain plans had submitted. When the plans fix their data, which we monitor closely as well, the price increases that you might have thought were there really weren't there. Nobody is paying those price increases at the counter.

MR. WAXMAN. I hate to do that, but I do want to interrupt you because--

DR. MCCLELLAN. You don't need an explanation. It is your prerogative.

MR. WAXMAN. I just think if people who have to figure out this whole thing, seniors, they look at the myriad co-pays, the premiums, the deductibles, and they have no idea what they are really paying for and I don't think that we can say competition is working or even can work in this kind of atmosphere, but I want, in the few minutes I have left, to ask you about these Medicare and Medicaid dual eligibles. Medicaid has a provision that requires via a rebate system, the Federal government receives a drug manufacturer's best price on prescription drugs. Suddenly they are all being switched over to Medicare and this best price rebate is no longer in effect. The result is a multi-billion dollar giveaway to the drug manufacturers.

Dr. Steven Sondermeyer, University of Minnesota, estimated drug prices for these dual eligibles are now 20 to 30 percent higher than the Medicaid program. My staff has estimated these higher prices will result in a windfall of $30 billion for drug manufactures, all of this at taxpayers' expense. Can you explain the rationale for me? It makes no sense that all of a sudden the Federal government is paying billions of dollars more for drugs that we were getting at a discount prior to January 1. This looks like a multi-billion giveaway to the drug manufacturers.

DR. MCCLELLAN. The drug savings from the Medicare prescription drug program usually exceed the drug savings available for Medicaid. We are seeing that in a couple of ways. Number one, States that are participating in our reimbursement program have differentials made up by us because the total cost, the total payments for the drugs by the drug plans, are less than what they were paying in Medicaid. And number two, as you saw from our own independent actuaries report, the cost of this drug benefit is much lower than projected because they are getting savings on average of 27 percent. That includes substantial rebates that are larger than the savings that Medicaid--

MR. WAXMAN. I want to dispute that because independent Wall Street analysts have estimated that the higher prices, and there are higher

prices, are going to result in over $1 billion in manufacturer profits in just five drugs. Other industry analysts have estimated the windfall, in just the first year, is going to be over $2 billion and more importantly, Dr. McClellan, your own data tells a different story. Just last week CMS actuaries estimated that the Medicare drug plans would obtain drugs of 20 percent off of the manufacturer's listed average wholesale price and several months ago, the Congressional Budget Office produced the same estimates for the Medicaid program. They found that the Medicaid program receives an average discount that is 25 percent larger than this CMS estimate, so I am not sure that you are getting the accurate information when you say Medicare prices for brand name drugs are even better than the Medicaid best prices. I would like you to give us some more details that back up this--

DR. MCCLELLAN. We have a comprehensive report that we are releasing that we will share with you that reviews all of this and I'll just repeat what our independent actuaries have found. What they found is number one, the costs of this drug benefit are much less than expected because of this very aggressive price negotiation and not only that, the cost of their forecasting for overall prescription drug spending in the United States has gone down significantly, they said because of the drug benefit and the aggressive price negotiation. Second, as the independent actuaries have said, any additional government negotiation using the Medicaid approach would not lead to lower costs of this program.

MR. WAXMAN. Aggressive price negotiation would be if the Federal government negotiated for the best price for all the people that are getting these drugs. That is prohibited in the legislation and I do believe that we will get the backup for your comments, but I do believe that the Medicaid price has always been and continues to be a lot cheaper than what we are paying for the same people for the same drugs now that they are switched over to Medicare.

DR. MCCLELLAN. We do need to make sure our staff goes over our results with your staff so hopefully we can get to a consistent answer here, but the numbers on the premiums, the numbers on the overall cost of the drug benefit, seniors around the country who are getting coverage for $20, $10 or even less are seeing the savings right now, made possible by the aggressive negotiation that is going on. I suppose you could potentially get more savings if we were more restrictive in what drugs people had access to. For example, the VA, that you cite in your study, has prices for--

MR. WAXMAN. Medicaid wasn't more restrictive than what they are--

DR. MCCLELLAN. Oh, Medicaid prices are not lower than ours and for the VA, six out of the top ten drugs used by seniors aren't on the formulary.

MR. DEAL. Dr. Norwood is recognized for questions.

MR. NORWOOD. Thank you very much, Mr. Chairman, and if, Dr. McClellan, I am going to stay with this subject because I think it is very, very important that we all understand this cost picture. Now, I hear you say that patients are going to pay less money for their meds.

DR. MCCLELLAN. Right.

MR. NORWOOD. Is that a correct statement?

DR. MCCLELLAN. That is correct.

MR. NORWOOD. Will the taxpayer pay less money for their meds than they might under any other circumstances?

DR. MCCLELLAN. Well, I hesitate to say under any other circumstances. I can tell you that--

MR. NORWOOD. Well, specifically to the circumstance we know about, then, which would be Medicaid.

DR. MCCLELLAN. Sure.

MR. NORWOOD. Say it a different way or say it so this old country boy can understand it.

DR. MCCLELLAN. Okay, well let me say it again. Usually the drug prices under Medicare, counting for the rebates, are less than the drug prices under Medicaid. We have good first-hand experience on this now. You know, we are reimbursing some of the States for the cost that they have incurred for some of their dual eligibles during this transition period. The plans are paying them back first, but because in some cases the States paid more under Medicaid than the plans are paying for their drugs, we are making up that difference. So that is adding a little bit to the cost or implementation of the program. Another piece of evidence is the fact that the cost of this drug benefit is turning out to be more than $5 billion lower this year alone because of the aggressive price negotiation that is going on.

You asked if it is possible to get more savings. It might be if we had even more, if we had more restrictive drug formularies, if we had more restrictive prior authorization, but I don't want to do that. I think there are a lot of beneficiaries who don't want to be in an HMO-type plan where, as in the VA system where six out of the top ten drugs aren't even covered on the formulary.

MR. NORWOOD. Now go there a little bit. Explain that some more. The VA cost of medications we buy, the government, from pharmaceutical companies at the Veterans Administration, that whole purchase is generally lower, you are saying.

DR. MCCLELLAN. They do have lower drug cost, but they have some very important differences. Number one, you cannot get those drugs at a retail pharmacy in your community. You have to go to the pharmacies that are within this government-run system; there are not very many of those and that is why 75 percent of the drugs prescribed in the VA system are done by mail order. Many seniors don't want to go to mail order, they want to use their local retail pharmacist.

The second difference is that these drugs are prescribed within what is essentially an HMO-type of coverage arrangement. They are salaried doctors that work for the government in only a limited number of facilities that prescribe the drugs and they work within the VA system. Many seniors don't want to get their care through an HMO-type of arrangement.

A third difference is in how the formularies work. Under the Medicare program we have had fairly broad requirements about access to medicine, so 80 or more out of the top hundred drugs are typically covered by a plan. The numbers in the VA are significantly less. Six out of the top ten drugs are not covered, for example.

MR. NORWOOD. So Mr. Waxman, his view of it is that the pharmaceutical industry is getting this windfall. Your view of it is that we are actually offering a darn good drug plan. For seniors it is costing more.

DR. MCCLELLAN. And I like to go by the numbers and one source of numbers is our independent actuaries and what they said in their forecast about national health expenditures which they just made recently. Just a week ago, they said that their expectations about total prescription drug spending in this country are now much lower in the years ahead because of the very aggressive price negotiation and cost control steps going on in this program, so you have got millions more seniors getting drugs at a much lower cost, you have got total drug spending going down. Those seem like pretty good steps.

MR. NORWOOD. Well, we need to make sure everybody understands this as you gather more and more information. My last minute I have left, make me feel good about what you are going to do to police the insurance plans. Just make me feel better.

DR. MCCLELLAN. Well, this has come up a lot and I want to be very clear that we take our oversight responsibilities very seriously. We have already implemented a program where we are monitoring the wait times on the plans' call lines for beneficiaries, for pharmacists, and we are going to do it for--

MR. NORWOOD. Are they improving their wait call times?

DR. MCCLELLAN. They have improved significantly. They were very long in the early part of January with the data problems. They have

gotten significantly better. I think there is still room for more progress. We are also tracking complaints that come in about individual plans. What we are focusing on right now is fixing each individual complaint as it arises, but over time, we are going to be able to see patterns and where we see patterns in plans, plans that are doing a relatively bad job, we have got further enforcement actions that we can take that go all the way up to suspending them from the Medicare program.

MR. NORWOOD. How long does it take to get patterns? Five years, ten years?

DR. MCCLELLAN. We are going to have reports from the plans over the next several months. We expect that that information will be available within just a few months.

MR. NORWOOD. Thank you, Mr. Chairman.

MR. DEAL. Ms. Baldwin is recognized for questions.

MS. BALDWIN. Thank you, Mr. Chairman. Some States waded into the territory of drug benefits prior to the passage of the MMA. Wisconsin was one of those States, that under a pharmacy plus waiver initiated a prescription drug plan called Senior Care. The program has been enormously popular, cost effective, and I would argue very successful. Upon passage of the MMA, we were very concerned that Wisconsin might be forced to end Senior Care. I am wondering how it would interact with the new Part D program and I was very pleased that the waiver was extended to the year 2007 and I thank you for your efforts in that regard and that in addition, Senior Care was considered creditable under Part D.

During the enrollment period for Part D we experienced, in Wisconsin, a substantial increase in enrollment in Senior Care. It seems to be one of the preferred plans, 6,000 new enrollees over the past several months. And what we are finding in terms of our own analysis is that almost all who qualify for Senior Care in the State of Wisconsin, for them the benefit is more generous and at a lower cost, so it is very cost effective for the citizen.

The most frequent request that I get from my constituents, in talking about all this is please make sure they, that would be you, let us keep Senior Care into the future and I know that the waiver review process looks at a wide range of factors, but my constituents have asked me and frankly, the entire Wisconsin delegation to fight for Senior Care. So I am asking first off, what assurances can you give me that Wisconsin's seniors, or give me and Wisconsin's seniors that Senior Care will continue beyond the year 2007 and also, how much weight do you place on issues like customer satisfaction and cost effectiveness in your waiver review?

DR. MCCLELLAN. Well, Congresswoman, first I hope our commitment to Wisconsin's seniors has been evident already from the fact that we developed the Pharmacy Plus waiver program and approved the Senior Care program in the first place. Secretary Leavitt worked very closely with Governor Doyle and with the rest of the delegation. You are absolutely right. There is a strong commitment from the Wisconsin delegation to make that program work.

MS. BALDWIN. Everyone sees that 2007 date out there in the future, so there is so much anxiety.

DR. MCCLELLAN. Well, Congressman Ryan and Congressman Green, they all have been working very closely with us to make sure that we keep this program and the people it serves, served effectively. The arrangement that Governor Doyle worked out with Secretary Leavitt involved not only continuing the program in this year in its current form, but also making available a wraparound version, much like the State of Illinois has done, or other States with Pharmacy Plus waivers have done, to have it work even more smoothly with the Medicare prescription drug benefit and we are pleased that that program is continuing now. I am glad that more people have enrolled in it. There was a big gap, as you know. That program had been around for a couple of years and only 50 percent or fewer of those who were eligible signed up for it, so I am glad that we are getting more people enrolled. In the same period of time we have seen 80,000 people sign up for the Medicare prescription drug plan, so we also want to make sure that the Senior Care works well directly with the Medicare prescription drug plan. So we are going to keep up this close relationship with the Governor and the State to make sure this happens going forward.

MS. BALDWIN. Well, I know in terms of that negotiation, I guess the real question is the degree to which this is an incredibly cost-effective and popular program; creating new demands on it is something that you just mentioned and discussed, but to what degree is the current success of the program weighed in the request for an extension beyond 2007 because, you know, just as it is, it is cost-effective, wildly popular for those who qualify and I would absolutely agree that they set up and structure the program in a way that not everybody who is 65 and older qualifies for it, but for those enrolled, it is, you know, again, the benefit is more generous and at a lower cost to the Federal government.

DR. MCCLELLAN. It is. It has taken, by the way, some time for those enrollment numbers to get up. Starting in 2002 and you know, as we are talking about getting more enrollment in the Medicare program, also a voluntary program, I am pleased that we are kind of running ahead of the numbers that Senior Care was able to get in its first couple of years and that we are adding more onto Senior Care now as more people are

getting coverage through the Medicare drug plans, but we will keep working together closely just as we have done in Illinois. Illinois had a Pharmacy Plus waiver, too, where it is now wrapping around the benefit, saving the State money, working--

MS. BALDWIN. Let me just interject because my time has ended. I do have a follow-up question I will submit in writing about those 2,000 plus Senior Care beneficiaries who were auto-enrolled mistakenly in another Plan D program.

DR. MCCLELLAN. Absolutely.

MS. BALDWIN. We do want some follow-up on that, thank you.

MR. DEAL. I thank the gentlelady. Dr. Burgess is recognized.

MR. BURGESS. Thank you, Mr. Chairman, and again, Dr. McClellan, thank you for your forbearance. If it is all right with you, I am going to take a few questions from the testimony of my constituent, Mr. Song, who is going to be heard from later, but this is perhaps an opportunity for him to get his questions answered more quickly.

DR. MCCLELLAN. Sure.

MR. BURGESS. One of the issues he brings up is why has there been no prompt pay provision within the Medicare plans and why can't there be an electronic fund transfer so the pharmacies don't have this extremely long time in their accounts receivable?

DR. MCCLELLAN. Good question. I am concerned about long waits, particularly if they are waits that weren't contemplated in the contract the pharmacy has with the drug plan. Many plans are paying using electronic funds transfers. Some are paying by check. I understand that that is not unusual in the industry. Many drug plans, or many health insurance plans, pay by check. What we have the authority to do is to make sure that the drug plans follow their contractual provisions. I want to be very clear about this. If a pharmacist is not getting paid according to the contracts, if they are facing undue delays in reaching the plan, we want to hear about it and we will take further action. We have done that already. That has brought the wait times way down, and we are seeing checks going out on a regular basis, payments going out on a regular basis, so we do want to make sure that those contracts are enforced.

MR. BURGESS. We might consider making electronic fund transfer just part of any plan that we accept in the future and encouraging those plans to go on that. What about the issue of drug plans being able to put a logo on their card?

DR. MCCLELLAN. This is what is called co-branding and we asked for a comment about this going into 2006 and got some comments back, but just like a lot of issues with a new plan that people haven't experienced before, I think the experience since then has led people to change their views and so I think some of the comments that we got in

2005 would be different than they are in 2006. Looking ahead, we have put out for comment what we should do with this co-branding approach in the future. That is out for public comment right now. I am sure we will hear back from pharmacy groups on this; I already have and I am sure we will be taking account of those comments as we go forward. We have already worked with many of the drug plans to have them make clear that if they do put any logos on their cards, they also communicate that other pharmacies are in their network and can be used and we are looking at whether further steps should be taken and that is out for public comment right now.

MR. BURGESS. Very well. What about standardization of dealing with formulary denials? Apparently, right now you just get the message back that a drug is not covered; the pharmacist, perhaps a physician's office has to get involved to find out why the drug hasn't been covered. Is there any way to standardize that process so that there can be an immediate communication of why the drug wasn't covered and the pharmacist will understand that and know how to remedy the problem?

DR. MCCLELLAN. You know, I have heard from many pharmacists about this. It reminds me of my own experience in medical practice where, as you know, different insurers require different forms. There just is extra work for the health professional. There is a group working right now, with our backing, made up of representatives from independent pharmacies, chain pharmacies, and the drug plans to accomplish just that kind of standardization and they have already made some real progress. They submitted some new code standardization ideas to, what is called the NCPDP, that is the standard setting body for pharmacy transactions. They have already submitted some ideas. I expect them to do more just in the next few weeks to help make further progress on this issue. It is a very good idea.

MR. BURGESS. Do you think that would streamline the process?

DR. MCCLELLAN. I do. I think that is going to help make this work better, but I have got to tell you, I don't want us to just come in and put out what we think are the right standards. I would rather have the standards come from leadership from the pharmacies working with the plans on both what is feasible and what is going to be most effective from the pharmacies.

MR. BURGESS. And I assume you will hear from the community pharmacists in that regard, if you haven't already?

DR. MCCLELLAN. Absolutely.

MR. BURGESS. Okay. What about the enrollment period where a patient signs up for a plan on February 28th and March 1st walks in, presents their card, said I need my stuff? Apparently, that is happening. Is there any way to make it a reasonable enrollment period?

DR. MCCLELLAN. Well, the pharmacies have borne the brunt of that short turnaround. That basic feature is in the statute. We are looking at what we can do to change that going forward, but that is an area where we may need to keep talking with you. There have been some ideas from the plans from us about in the future having more of a delay period between when a person enrolls and when that enrollment becomes effective, so that is an issue that we are going to see if we can address. It is very hard to address in the extreme short term because it requires systems changes and also there are these potential statutory obstacles in the way.

What we have done, instead, in the short term, is engage in a broad education and outreach campaign through our own web site and 1-800-MEDICARE number, through working with all the drug plans and through pharmacies and advocacy groups to let people know that signing up early in the month provides plenty of time for them to get their card and have the systems work well when they start using their prescription drug coverage early the next month, or at least to wait a few weeks. You know, if you can sign up on your own, if you get your application in, wait a week or so, you will get a letter back from your plan that gives you proof of the insurance; wait a few weeks, you will get a drug card. If you can sign up that far ahead, you have a very high likelihood of having a good, smooth experience the first time you go in to the pharmacy, so we are very much stressing those educational messages right now.

MR. BURGESS. Yes. You know that doesn't always work out. Mr. Chairman, could I ask that we consider having a repeat of this hearing the first week in May so we can revisit the concept of the May 15th deadline?

MR. DEAL. I can't make a promise about an exact date for a hearing, but we will certainly consider it. I think there has been a request from both sides to do that.

DR. MCCLELLAN. And I will look forward to seeing you again.

MR. DEAL. The gentleman's time is expired. Mr. Pallone.

MR. PALLONE. Thank you, Mr. Chairman. I am going to try to get some quick answers from you if I can because I have a bunch of questions. First of all, following up on what was just said about the prompt payment and the co-branding, because this was a big issue when I went to visit my pharmacies. Let me just ask you, would you be in favor of legislation that would require, for example, two weeks prompt payment for electronic or say, 30 days for, you know, written by check, and also, on the co-payment, I mean, co-branding? We could simply prohibit co-branding and have penalties for it. What would you think of legislation--

DR. MCCLELLAN. Well, on the first issue, on the timing of payment, that is something that would require legislation. Under the program, the pharmacies contract with the drug--

MR. PALLONE. Right, but let us assume that I put in the bill, I will gladly do it, let us say 15 days for electronic, 30 days for written and prohibit co-branding.

DR. MCCLELLAN. One concern is that some plans are paying on a faster schedule than that. Some of them are doing 10-day--

MR. PALLONE. No, I mean at a minimum.

DR. MCCLELLAN. Well, I am concerned about us putting restrictions on contracts that may work better.

MR. PALLONE. Well, you are not necessarily in favor of it, then?

DR. MCCLELLAN. Right. On co-branding--

MR. PALLONE. Co-branding.

DR. MCCLELLAN. --we are, for the 2007 year, for the next round, when people are going to have cards printed up and so forth, we have asked for public comment on whether and how we should change--

MR. PALLONE. But you are not in favor of prohibiting it at this point?

DR. MCCLELLAN. I am not--I don't think we need legislation. I think we can get input from the pharmacy groups.

MR. PALLONE. Can you do it without legislation?

DR. MCCLELLAN. Yes, and based on that input we will put out further guidance on what should be--

MR. PALLONE. All right. I want to go back to some of the questions that Mr. Dingell asked you for because I have to be honest with you, this whole issue with the prior authorization and appeals of formularies, I think this is going to get worse. I mean, the transition period, I guess, ends sometime this month and I just think the mass confusion that we have now, which is out there. I mean, I am not reading it in the newspaper, I am getting it from my constituents, is only going to get worse and if we don't have some way to, you know, standardize appeals of formularies or deal with this prior authorization, I think it is only going to get worse, so I mean, there was an article in the New York Times that said one plan had 39 different forms to use for prior authorization. Do you have any plans to require a standard form for appeals to minimize this kind of confusion?

DR. MCCLELLAN. Well, I don't want to sound technical, but the process that the plans go through is asking for an exception. If that process doesn't get worked out smoothly between the beneficiary and the plan, they can appeal to Medicare and Medicare does have--

MR. PALLONE. But the problem is that people don't even know about this, Doctor. They don't even know.

DR. MCCLELLAN. Well, they do. Well, there are lots of places they can get that information, including from the information the plan sends them.

MR. PALLONE. Yes, but the drug plans are not adequately notifying them, believe me.

DR. MCCLELLAN. Let me turn to what we have done to make this--

MR. PALLONE. Yes, but I just want to ask you this because I have got to ask you a couple more things. You don't have any plans to require a standard form of appeal right now?

DR. MCCLELLAN. We have a model form for exceptions and we are working right now with plans, pharmacies and physician groups to get an effective standardized form widely adopted and that is something we will be looking at and grading the plans on.

MR. PALLONE. But it is not required at this point?

DR. MCCLELLAN. Well, it hasn't been widely adopted at this point because this is a new program.

MR. PALLONE. Okay.

DR. MCCLELLAN. And we are working with all of these parties--

MR. PALLONE. But it is not required? Just yes or no, it is not required?

DR. MCCLELLAN. It is not required at this point.

MR. PALLONE. Okay.

DR. MCCLELLAN. But many plans are using the model form.

MR. PALLONE. All right, let me give you--I have only got about a minute and a half. Can CMS provide us some data on the Part D exceptions and appeals? In other words, can we get the number of requests for exceptions and appeals under Part D that have been filed, the types of exceptions and appeals filed, the disposition of those requests? I have got a whole series of questions.

DR. MCCLELLAN. The plans are required to provide that information as part of the--

MR. PALLONE. But have you collected that data so far?

DR. MCCLELLAN. They will be submitting it to us on a quarterly basis and after it has come into us and we clean it up, we will make it available.

MR. PALLONE. Mr. Chairman, if I could just, with your permission, ask some written questions about that data and whether it could be made available?

DR. MCCLELLAN. We would be happy to answer your written questions.

MR. DEAL. Without objection.

MR. PALLONE. All right. Then the last thing. I have to ask you about New Jersey because, you know, in our State, we are putting out so

much money and everybody is so concerned because when Governor Corzine and his staff met with you, I guess, within the last week, you were unequivocal stating that New Jersey would be made whole in terms of both dual eligibles as well as our PAAD program, which is our own New Jersey program, but today we are told that with some of the Governor's staff and with the New Jersey Medicare people, the agency backed away from some of those statements, so I am concerned about where we are going and I just wanted to, again, with the Chairman's permission, if I could give you some written questions about how New Jersey is going to be reimbursed and whether or not that original commitment is going to be met or if there is some change.

DR. MCCLELLAN. Well, we have been working very closely with the State. As you know, the reason why New Jersey has got so many more claims than just about every other State is that most of those are not dual eligible beneficiaries. Those beneficiaries are now in their Medicare plans, are getting--

MR. PALLONE. But the impression given, based on the conversation you had with the Governor in the last few days was that the other people who are under our State plan that are not dual eligibles, that we would also be reimbursed for that.

DR. MCCLELLAN. We have, as part of the reimbursement program, a standard template for paying for, for making sure States are reimbursed for their dual eligible beneficiaries and for low-income beneficiaries. New Jersey has some beneficiaries who aren't in either of those categories. For the ones that are enrolled in Medicare drug plans, some of them aren't even enrolled in Medicare drug plans yet, so there is no way we can pay for them. For the ones that are enrolled, we are going to try and work with the States, with the State of New Jersey to get those resolved, too, but that is kind of a unique issue for the State of New Jersey. It is not something--

MR. PALLONE. With the Chairman's permission, if I could just ask some questions to follow-up on this?

MR. DEAL. The gentleman may submit his questions in writing. I am going to ask the members if they would try to abide by the time clock. We have got some members on the second panel that are going to have to leave and we are not even going to get to their testimony if we don't speed this process up just a little bit.

MR. PALLONE. Thank you.

MR. DEAL. Mr. Ferguson.

MR. FERGUSON. Thank you, Mr. Chairman. Thank you, Dr. McClellan, for being here and thanks for your patience and your helping to wade through so many of these issues and a lot of general questions have been asked. I want to hone in on a more specific issue, not the

implementation, generally, but an issue that I think, my understanding is, could have easily been resolved. It would not have resulted in any administrative or budgetary burdens. It is a critical healthcare issue to thousands and thousands of seniors who rely on medication, prescription medication to raise their good cholesterol in an effort to prevent heart disease. I just had my physical. My good cholesterol is okay, but it might not be for the rest of my life, so it is something that obviously all of us need to be focused on.

The issue concerns reports that CMS is now informing plans that Part D will not cover Niaspan, which is an important prescription drug. It was approved by the FDA specifically to reduce the risk of recurrent heart attacks and to treat dislipodemia. I have a couple of questions and a couple of assumptions that I want to ask if you could confirm this. A lot of cardiologists have contacted our office, as well as folks from your operation, your Deputy Director of Plan Policy and Operations, Gary Bailey; your Chief Medical Officer, Dr. Kellman; they have acknowledged that Niaspan has an important place in the treatment of dislipodemia. Do you agree with the assessment that Niaspan is a valuable medication to patients?

DR. MCCLELLAN. It is. As you said, that is on the FDA label. What is also on the FDA labeling is that it is a vitamin, which means that it is in one of those categories that is excluded.

MR. FERGUSON. I am going to get to that.

DR. MCCLELLAN. Okay.

MR. FERGUSON. Isn't it, in fact, the most effective treatment for treating, for raising HDL?

DR. MCCLELLAN. Well, there are many effective treatments for dislipodemia and niacin is, a very effective way to raise HDL for patients who can tolerate the side effects.

MR. FERGUSON. What other ways can patients reach their HDL goals without--

DR. MCCLELLAN. Dietary change, some of the other medications that are available, non-vitamin medications that are available by prescription.

MR. FERGUSON. But for probably literally thousands and thousands of seniors, this is the best way, would you agree?

DR. MCCLELLAN. This is definitely a treatment that is widely used by seniors and is very effective in raising HDL.

MR. FERGUSON. Okay. Well, the vast majority of the plan formularies that were initially approved by CMS covered it and now, you know, when seniors were deciding which plan to choose, the information available to them on the CMS formulary finder indicated that this was covered on many of the plan options and it wouldn't have been

surprising to patients and their physicians, since it is already covered by most private insurance plans. All 50 State Medicaid plans cover it.

It has appeared on the formularies for numerous Medicare discount drug cards and recently, on the web site, your web site, you said that this is considered now a prescription vitamin, which is excluded because of its technicality, from definition, for Part D's definition of a drug. This is a prescription drug. You can't just go in and buy it off the shelf. You need a prescription from your doctor to buy this product. It is a prescription medication. And now the decision, starting June 1 of this year, that you are actually going to pull coverage; people who currently have coverage for this under Part D are not going to have their coverage for this pulled. Is this the final word on this from CMS?

DR. MCCLELLAN. Let me clarify that last point. This is a prescription vitamin and unfortunately, no matter how many times I ask them, our general counsel gives me the same answer every time, which is that the law specifically does not allow Medicare to pay for prescription--

MR. FERGUSON. But it is paying for it now.

DR. MCCLELLAN. And that is why there has been this further clarification. The plans are not required to drop this from their coverage. In fact, many plans cover a number of drugs that are excluded; they just don't get any subsidies from Medicare in doing so. They can provide discounts, as they did under the discount card. In some cases, they can even provide some coverage, but it has got to be built into the cost of the benefit that they are providing, itself. It is not something that we are allowed, under the law, to provide Medicare subsidies to pay for.

MR. FERGUSON. The American Heart Association, the American College of Cardiologists, and American Pharmacists Association have issued alerts warning of very serious health consequences for people if they don't have coverage for this drug. You are aware of that?

DR. MCCLELLAN. Well, many people didn't have coverage for this or any other drug before and thanks to the new drug benefit, they have got it now and they are getting a lot more savings on their other drugs. That is why seniors, with that $1,100 in average savings are going to be in a lot better shape to get any drug that they need, including drugs that are excluded from the Medicare program right now, but this is a statutory issue.

MR. FERGUSON. So there is, what you are suggesting is there is absolutely no administrative action that CMS can take to solve this problem?

DR. MCCLELLAN. I will ask our lawyers again, because I have had a lot of these conversations already, and I would be delighted to continue to work with you and your staff to see if we can find a way to resolve

this, but from the FDA labeling, it is very clearly a prescription vitamin. From the statute, vitamins are very clearly excluded from what Medicare--

[The information follows:]

INSERT FOR THE RECORD OF THE HON. MARK MCCLELLAN, ADMINISTRATOR, CENTERS FOR MEDICARE & MEDICAID SERVICES

CMS has issued more recent policy clarification regarding prescription Niacin products. This policy clarification supersedes our February 3, 2006 letter.

The Food and Drug Administration has determined Niaspan and Niacor to be safe and effective drugs, used therapeutically for the treatment of dyslipidemia, and that they do not serve as nutritional supplements or address vitamin deficiency. Additionally, these products are used at dosages much higher than appropriate for nutritional supplementation. For these reasons, CMS has superseded its initial February 3, 2006 letter and determined that these products should not be considered prescription vitamins for purposes of Part D coverage. The new policy guidance does not require plans to add these products to their formularies for 2006. However, for the 2007 contract year, prescription Niacin products should be considered for formulary inclusion similar to all other Part D drugs.

MR. FERGUSON. But it is not Vitamin C that I can go buy off the shelf.

DR. MCCLELLAN. I know.

MR. FERGUSON. You need your doctor to tell you that you need this.

DR. MCCLELLAN. Unfortunately, the statute says vitamin and it doesn't make a distinction between Vitamin C and niacin.

MR. FERGUSON. Well, it is a very unfortunate technicality for folks who rely on this for their HDL. Mr. Chairman, I am wrapping up and I know I am done.

MR. DEAL. The gentleman's time has expired.

MR. FERGUSON. I appreciate the great work you have done on the implementation of this program. I know this is a vexing issue, but I think it is a hugely important issue to seniors who need this for raising their--

DR. MCCLELLAN. And I want to be clear that the plans can offer discounts on niacin that people didn't get before. They are offering discounts on all medications. In many cases they can provide benefits in this area. We just can't provide a Medicare subsidy for it.

MR. FERGUSON. I would appreciate your looking into it again.

DR. MCCLELLAN. Okay.

MR. DEAL. Ms. Eshoo, you are recognized.

MS. ESHOO. Thank you, Mr. Chairman. And again, I want to urge you to hold more oversight hearings on this, on a whole variety of issues. I think that that has come across from both sides of the aisle and I think that we owe it to the people that we represent to do so. Dr. McClellan, I

have several questions. First, how much do you owe the States now on dual eligibles?

DR. MCCLELLAN. We have not gotten claims from all of the States.

MS. ESHOO. How much do you owe from those that have put in their claims?

DR. MCCLELLAN. Oh, in many States it is a very low number. Florida, less than 100; Pennsylvania, less than 5,000 claims so, you know, a very small amount of dollars.

MS. ESHOO. It is much larger in California that I know of, in terms of what is being reported.

DR. MCCLELLAN. Yes, that is right and--

MS. ESHOO. Do you have enough money in your budget, are you forecast, did the forecast--

DR. MCCLELLAN. We do, because most of these costs are not going to be additional costs. We are going to reconcile the payments with the drug plans. These are payments that the drug plans should've been making.

MS. ESHOO. Okay.

DR. MCCLELLAN. And so the drug plan has been very clear.

MS. ESHOO. All right, on to the next question. How many people have actually electively signed up for Part D?

DR. MCCLELLAN. Completely on their own.

MS. ESHOO. Elected, elected.

DR. MCCLELLAN. Over 5.5 million. There were another more than five million who elected to join a Medicare Advantage plan, including many people in your fine district who are now getting more prescription drug coverage, so millions of people have signed up for plans that include this--

MS. ESHOO. Well, they are not the numbers that have been put out, generally, in the press. That is why I am asking that because there is a difference between 25 million and 5.5 and I don't think that is nitpicking, but I just wanted to hear what you have to say about it. I should have started out with this observation and I am going to say it. I know that I am inside the beltway. I have to tell you, I have been here from the very beginning of this hearing and our discussion here and what is going on outside of this place are two completely different things, two completely different things. And if anyone thinks that we are even in the ballpark on this, I mean, what it says to me more than anything else is that Congress is not listening.

I mean, there are huge problems out there with people and that is really quite stunning. I have to say that, and I say that, having sat through this. This is an almost out-of-body experience today. I don't wish anyone any ill or harm or anything. I wish that this was something

that was really working well and that we had to work through some wrinkles, because it is large and it is new, but that we would bring people along. That seems to be the notion that we are operating under here, but I want to say to Members and to you, Dr. McClellan, that is not what is going on outside of here. It is a completely different thing. People are really up in arms about it, so you know, I hope we have a reality check. Maybe that is what oversight can do, but if we are going to pretend that we have just got a few things to iron out here, we are really going to miss the mark with the American people and so on the issue of that enrollment deadline, I know that Mr. Bilirakis raised it, and said that he would like to work with you on that. I want to sign on to that.

I think that that enrollment deadline really needs to be stretched and I think, in many ways, it goes to the heart of one of the larger problems that people are experiencing, just generally, with the whole plan and they shouldn't be penalized for that. It is Congress that designed the darn thing, you know, and if, in fact--this is not insinuating that people aren't sharp enough or good enough or intelligent enough--they really are having problems with it and I don't think it is fair if they are penalized. And the penalty accrues, as well, as I understand it, so would you support that? Did you say that you supported--

DR. MCCLELLAN. I said I absolutely want to keep talking with you about this issue. What, I guess, we are most focused on right now is that we have seen millions of people find out from--

MS. ESHOO. Well, Dr. McClellan--

DR. MCCLELLAN. --their plan and we want to make sure that everyone will take advantage of it as soon as possible.

MS. ESHOO. I really--just a second. Just a second. How many Medicare beneficiaries are there in the country?

DR. MCCLELLAN. Altogether, over 40 million.

MS. ESHOO. All right. So now, we have had 5.5 million that have elected to sign up, so now if you want a robust program, you believe in it, you are administering it, all right?

DR. MCCLELLAN. Right.

MS. ESHOO. Might I suggest to you that we have got a ways to go? So you know what? If you penalize people, you are chasing them away from what you are advocating, so I would urge you to think this one through and all I can do is to suggest that. Secretary Leavitt has indicated--

MR. DEAL. The gentlelady--

MS. ESHOO. If I might just finish this one?

MR. DEAL. Okay.

MS. ESHOO. That many of the insurers will drop or some insurers, he said many, insurers will drop out of the Medicaid program, the

Medicare program next year. Is there a plan on how to handle the beneficiaries who would no longer have coverage because their carrier pulled out?

DR. MCCLELLAN. Yes, there is.

MS. ESHOO. And is there a grace period?

DR. MCCLELLAN. Well, remember that a lot, what I think Secretary Leavitt was talking about is competition working. Not every one of these plans, and Chairman Barton mentioned this, as well; not every one of these plans is equally popular. Many plans have seen a large number--

MS. ESHOO. Yes, we have 132 in California.

DR. MCCLELLAN. Some were offered that not many people are signing up for.

MS. ESHOO. Will there be a grace period or something for people?

DR. MCCLELLAN. Absolutely, and if the plans continue through the end of the year, as you know, there is another opportunity for people to choose a plan, maybe a better plan at the end of this year. At that point, we will have a lot more information about which ones have done well and which ones have done badly, and probably a lot of people are going to want to switch plans then, anyway. We will be working to make sure that everyone knows if their plan is not going to be around.

MS. ESHOO. As long as they are taken care of, that is what I want to know.

DR. MCCLELLAN. They will have an opportunity--

MS. ESHOO. I am still waiting to hear back from you on the geographic reimbursement adjustment last Thanksgiving.

[The information follows:]

INSERT FOR THE RECORD OF THE HON. MARK MCCLELLAN, ADMINISTRATOR, CENTERS FOR MEDICARE & MEDICAID SERVICES

In the proposed physician payment rule for 2005, CMS proposed modifications to the California GPCIs. This proposal was based on a budget-neutral adjustment to GPCIs within the state. The California Medical Association rejected that proposal because it did not provide for new money, which CMS does not hae the authority to provide. The Association also sent a letter to CMS at that point stating that their prefered resolution was a legislative change. CMS' approach to intra-state GPCI adjustments has been to obtain consensus from the members of the state medical association and then implement changes based on that consensus. The California Medical Association was not able to achieve consensus on a budget-neutral plan for adjusting their state's GPCIs and CMS is reluctant to make changes which would take money out of several counties in the state to the benefit of other counties, if the members of the California Medical Association have not been able to achieve consensus on that matter. At this point, we understand that the CMA intends to pursue a legislative fix, rather than attempt to obtain consensus on a budget-neutral adjustment.

MR. DEAL. Mr. Allen, you are recognized for questions.

MR. ALLEN. Thank you, Mr. Chairman. Dr. McClellan, I do have a bit of Congresswoman Eshoo's feeling that this is disconnected in too many ways from what we are hearing back home. Just to give you one example, you said that not one plan had removed a drug from its formulary. We started to get calls on January 20th or 21st, complaints from people who had signed up for a plan because of a certain drug and the drug had been removed from the formulary. I am just telling you, that is part of what we have been hearing, so the plans may not have been going through the process, but you know, we are getting those kinds of calls.

DR. MCCLELLAN. If you don't mind just quickly, on this point. This may be that Niaspan issue that we were discussing earlier where we had to direct plans that we could not provide financial support for, but that they are able to continue offering it for a while.

MR. ALLEN. Maybe. A couple of other things I just wanted to mention. One is your comments about the VA struck me as being a little bit off base. I mean, my understanding, correct me if I am wrong, the VA patients have access to all the drugs that are approved by the FDA and there are some popular drugs for which the VA gets a particularly good price and those are preferred, but if a doctor wants to or the patient needs the drug, they can get any drug and that that system is really the same kind of tiered system that Medicare uses. Am I wrong?

DR. MCCLELLAN. The VA does have a national formulary and you can get an off-formulary drug if you go through the exceptions and appeals process, and that is similar to the way the Medicare program works. What is different is that the Medicare drug plans generally have broader formularies than the VA. Six out of the top ten drugs aren't on the VA formulary; Medicare plans, in contrast, cover 80 out of the top hundred and we could have tighter formularies and some plans do. We don't require that because many beneficiaries--

MR. ALLEN. Right. Okay, thank you. I take the point. As long as we are clear on the difference. You will forgive us, I think, if we have some skepticism about estimates about cost because the history of this legislation is one that doesn't provide confidence in the numbers that are presented on cost and I can't go through all that with you now, but every time I hear words like the total cost is going to be less than Medicaid, I start backing off and wondering how that is going to be calculated. The cost of the entire program, the single thing that is going to determine, as we go forward over the next year or two, the single component of cost that may be the major drive here is not about negotiation, it is how many people sign up for the plan and if people don't sign up for this, for the Medicare Part D plan, the cost will be lower than projected, but fewer

people than expected will be getting their drugs, so the question of how we evaluate cost, I think, is important.

Our experience, I mean, you were saying the national actuaries were saying the total expenses will be lower and there will be a $5 billion cost lower this year. If that just means it is lower because fewer people sign up for the plans than anticipated, that is not a real savings at all, and I hope you would separate that in doing your evaluation.

DR. MCCLELLAN. I agree. The estimate is based on no changes in enrollment assumptions. The change is all because of lower negotiated prices and lower cost of the benefit.

MR. ALLEN. Lower than anticipated?

DR. MCCLELLAN. Lower than anticipated, that is right.

MR. ALLEN. But not lower, necessarily, than the VA or Medicaid?

DR. MCCLELLAN. Well, again, our actuaries don't think that any of those other approaches would save any more money.

MR. ALLEN. I understand, but one of your predecessors said that he would not support a negotiation because if he did that, he would just be setting prices. The clear implication was the price would be a lot lower if we negotiated prices. This is one more in a series of questions. I understand the Administration supports choice, and believes choice and competition will lower cost.

DR. MCCLELLAN. And it is doing so.

MR. ALLEN. But the Administration opposes allowing seniors to have a choice that will have a simple, uniform national plan run by Medicare, don't you?

DR. MCCLELLAN. Well, I haven't seen what that proposal is.

MR. ALLEN. That is a yes or no answer.

DR. MCCLELLAN. All of these plans are overseen by Medicare.

MR. ALLEN. I know, I know. But my question is--

DR. MCCLELLAN. The last time--

MR. ALLEN. Dr. McClellan, my question is simple. You oppose, do you not, having a national prescription drug plan run by and through Medicare, not private insurance companies where there would be a negotiated price?

DR. MCCLELLAN. Yes, because I haven't seen an approach to doing that that could deliver as much drug coverage at as low a cost as what we are seeing now. The last time--

MR. ALLEN. But you don't want people to have that choice. Well, the bill is H.R. 752.

DR. MCCLELLAN. What does it cost?

MR. ALLEN. So my question to you, beyond that, is real simple. You support choice, but that choice you are not willing to provide and

that is the simplest, cleanest choice available. One plan all across the country, all Medicare beneficiaries with a formulary set by Medicare.

DR. MCCLELLAN. A national plan with a national formulary would not give beneficiaries the opportunities for savings and better benefits that they are getting right now. I would be happy to hear more about this.

MR. ALLEN. I just haven't seen any details of this proposal, how much it will cost, what it would involve.

DR. MCCLELLAN. All these plans are Medicare plans that we are overseeing to make sure they meet all--

MR. ALLEN. Private insurance company plans that Medicare is overseeing, right? Private insurance plan.

DR. MCCLELLAN. And just as in previous Democratic proposals, there would be a privately run PBM or plan.

MR. ALLEN. With all due respect, Dr. McClellan, there are other proposals and we have had them and they are out there and I am sure your staff knows about them. Thank you.

MR. DEAL. All right, that concludes the questions from members of the subcommittee and I thank you for your patience. Dr. McClellan, it is interesting to me that we are only 60 days into this and it is also obvious that many adjustments have been made to overcome many of the initial problems. If we could just get a federally run program to operate as quickly as the private industry has been able to adapt and make changes, I think we would all be satisfied. Those of us who have Social Security beneficiaries who are waiting years for determinations with a government agency would say we would wish that in 60 days we could make the kind of adjustments that we have seen the private plans be able to make. We thank you for your attendance here today.

DR. MCCLELLAN. Thank you and I would just like to say for any beneficiaries who are watching to let them know that they can call 1-800-MEDICARE if they have any questions about what this program means for them. We can give them some personalized answers so they can take advantage of it. Thank you.

MR. NORWOOD. Chairman Deal. Chairman Deal.

MR. DEAL. Yes. I would like to ask unanimous consent that we insert into the record, right at this point, what the actual cost would be, what the score is on H.R. 752 for the record.

MR. DEAL. Without objection.

[The information follows:]

No cost estimate for H.R. 752 had been received from the Congressional Budget Office as of the date of printing for the hearing.

MR. DEAL. All right, thank you for being here, Dr. McClellan. I will call the second panel up and as you are coming--

MR. ENGEL. Mr. Chairman.

MR. DEAL. Yes.

MR. ENGEL. I am wondering if I could ask unanimous consent to ask Dr. McClellan a question.

MR. DEAL. Mr. Engel, you are not a member of our subcommittee. You have not been here for any of the hearing. We have got a second panel and we are going to lose some of the people if they don't get to testify because they have got airplanes to catch. I will allow you to ask questions in writing to Dr. McClellan, as other members have done for additional questions. I will allow you to ask questions at the conclusion of the second panel for anyone who is on that panel.

MR. ENGEL. Well, Mr. Chairman, with all due respect, the message we got from your staff is that I would be allowed to ask questions if I came in at the end and I was listening. I have been in my office.

MR. DEAL. Mr. Engel, I am not going to get into an argument with you. As you know, I have extended this courtesy to you in the past on times when, as today, you have never attended to hear the testimony of the witnesses. You have never been in the presence of the rest of us who have listened to the questions and the answers. In the past experience, your questions have repeated questions that members of the panel have asked. Now, I have been patient with you in the past, but we have eight people out here who are waiting to testify. They have been here since two o'clock today and I think, in all due courtesy to everybody, we need to get on with that second panel.

MR. ENGEL. Well, you know, Mr. Chairman, I have been in Congress 18 years and I have never, frankly, with all due respect, seen anyone as discourteous as you acting as a chair.

MR. DEAL. Well, I have been here for 14 years and I have never seen anybody come in at the last minute and expect, as a non-member of this subcommittee, to interfere with the rest of the operation.

MR. ENGEL. Mr. Chairman, I am a member of the committee. This has never been done--

MR. DEAL. You are not a member of this subcommittee.

MR. ENGEL. Well, particularly, when your staff has given misinformation. I was listening to every minute of this hearing in my office and I think it is an absolute disgrace, Mr. Chairman.

MR. DEAL. Well, thank you. I am glad you did. Well, I am sorry that you feel that way.

MR. ENGEL. Well, you don't have to be sorry.

MR. DEAL. If you would take time, and if you would come be with the rest of us, you would have the opportunity to ask questions.

MR. ENGEL. You are disgraceful.

MR. DEAL. We have been here for three hours, we will be glad to indulge you. Will the second panel please take their seats?

MR. ENGEL. Typical of the way your party runs this House.

MR. DEAL. Once again, thank you all for your patience. It has been a long day. I know you have had to sit and wait and listen, but we are pleased that you are here. I am going to introduce you all and then we will go directly into questions, your testimony, rather. I believe we have our two lay witnesses who have some time constraints and we are going to let you two go first, and we will get to you in just a second. First of all, and my introductions are not going to be in the way you are lined up the way the name tags are here. Ms. Susan Rawlings, who is President of Senior Services of WellPoint, Incorporated; Ms. Anne Dennison, who is a constituent of Dr. Norwood from Hiawasee, Georgia; Mr. Dennis Song, who is a constituent, I believe, of Dr. Burgess, as has already been referred to. He is here on behalf of the National Community Pharmacist Association. Mr. Tom Paul, who is the Chief Pharmacy Officer for Ovations, United Health Group; Mr. David Lipshutz, who is the Staff Attorney for California Health Advocates; Mr. Earl Ettienne, is that close enough? Okay. Who is the Senior Supervisor for CVS Pharmacy and I believe you are here in the Washington area, is that correct? Ms. Jude Walsh, who is the Special Assistant to the Governor's Office of Health Policy and Finance in Maine; and Mr. Marcus Hickerson, who is from Waxahachie, Texas. We are pleased to have you, as well. And we will do this in a little bit of reverse order and I hope the rest of you will understand on this. Ms. Dennison, we are going to start with you, if you would please make your statement.

STATEMENTS OF ANN DENNISON; MARCUS HICKERSON; DENNIS SONG, FLOWER MOUND HERBAL PHARMACY, ON BEHALF OF NATIONAL COMMUNITY PHARMACIST ASSOCIATION; TOM PAUL, CHIEF PHARMACY OFFICER FOR OVATIONS, UNITED HEALTH GROUP; JUDE E. WALSH, SPECIAL ASSISTANT, GOVERNOR'S OFFICE OF HEALTH POLICY AND FINANCE, STATE OF MAINE; EARL ETTIENNE, SENIOR RX SUPERVISOR, CVS PHARMACY; DAVID A. LIPSHUTZ, STAFF ATTORNEY, CALIFORNIA HEALTH ADVOCATES; AND SUSAN RAWLINGS, PRESIDENT, SENIOR SERVICES, WELLPOINT, INC.

MS. DENNISON. Thank you for the opportunity to come before you and talk to you about the new Medicare prescription drug benefit and

what it has done for me. My name is Anne Dennison. I am the daughter of a pharmacist. I am 72 years old and I live in the north Georgia mountains in a little town called Hiawasee. I have lived there for 28 years. I love it there. Our community is very tightly knit; it reminds me of the way communities were in the 1940s during the war. Everyone looks out for each other. The air and the water are clean and the people are friendly. Hiawasee is having its sesquicentennial celebration this March. In fact, it starts this Saturday and you all are invited to come on down. We would love to have you.

I have raised one son in Hiawasee, the other two were raised elsewhere. My son, Lewy, is here with me today. Over the years I have had a few different jobs. I have worked as a cashier, a bartender; I owned a restaurant, Ann's Place, and I also had quite a few health problems. I have congenital heart disease, diabetes, osteoporosis, allergies, and I have had bronchial pneumonia four times. I have also had two thyroid surgeries, one back surgery, and cancer removed from my tongue. Two different times I have had shunts put in and one of the biggest peptic ulcers the doctors in South Carolina had ever seen. So as you can imagine, I take quite a few drugs. I take 14 regular drugs and I take eight over the counter and from the health food store drugs.

I take Amaryl and Glucophage to control my sugar; a water pill called, and I can't pronounce it. It is hydro something choro something zide. That is all I can tell you. I got Synthroid and Amitriptyline for my thyroid; Digitek, Lipitor and Isosorbide for my heart; Coumadin and Acupril for my blood pressure; Allegra for my allergies; Actonel for the osteoporosis; and I carry Nitroquick with me in case of a heart attack.

With the help of my pharmacist, I chose a plan in November. I had no problems enrolling. I sent my application November 19th and I got a confirmation that I had coverage November 24th. I chose the AARP plan because it allows me to continue going to Rite Aid where I have been going. Also, I am active in the AARP and have used the discount card in the past.

Before the Part D benefit became a reality, I was paying out of pocket for my drugs. When I was paying for all of them, it was costing me over $700 a month. However, for a while I was getting eight of them for free through the nurse practitioner at my doctor's office in Hiawasee. That brought the cost per month down to around $300 some a month. My Social Security check is only $560 a month, so if you do the math you can see what buying the drugs I needed to stay healthy did to me financially. I would surrender my entire check to the pharmacy and the shortfall I would put on a credit card. When my sons found out about this, they began sharing the cost of the drugs.

And I have got another page. Excuse me. I have been to the pharmacy over a half a dozen times since my Part D coverage went into effect. Not once has the total for my drugs cost me over $10. I pay between $1 and $5 per prescription. Obviously, this benefit has been a tremendous blessing for me. I no longer have to rely on my sons for help. I have paid off the credit card debt I had run up and now I am thinking about trying to enjoy life a little with the money I have saved.

I appreciate the opportunity to come and tell you about my experience with Part D and thank you for passing this bill that has made such a difference in my health and my life.

[The prepared statement of Ann Dennison follows:]

PREPARED STATEMENT OF ANNE DENNISON

Chairman Deal and members of the Committee,

Thank you for the opportunity to come before you and talk about the new Medicare Prescription Drug benefit and what it has done for me. My name is Ann Dennison. I'm the daughter of a pharmacist. I am 72 years old and live in the North Georgia Mountains in a little town called Hiawassee. I have lived there for 28 years. I love it there. Our community is very tightly knit; it reminds me of the way communities were in the 40's during the War. Everyone looks out for each other. The air and water are clean and the people are friendly. Hiawassee is having its sesquicentennial celebration this March and you are all invited to come down.

I've raised one son in Hiawassee, the other two were raised elsewhere. My son Lewy is here with me today. Over the years I have had a few different jobs. I've worked as a cashier, a bartender and owned my own restaurant, Ann's Place. I've also had quite a few health problems. I have congenital heart disease, diabetes, osteoporosis, allergies & bronchial pneumonia. I've also had two thyroid surgeries, one back surgery, had cancer removed from my tongue, two shunts put in and one of the biggest peptic ulcers the doctor in South Carolina had ever seen! So as you can imagine, I take quite a few drugs. I take Amaryl and Glucophage to control my sugar, a water pill called Hydrochorothiazide, Synthroid and Amitriptyline for my thyroid, Digitek, Lipitor and Isosorbide for my heart, Coumadin and Acupril for my blood pressure, Allegra for my allergies, Actonel for the osteoporosis and I carry Nitroquick with me in case of a heart attack.

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I appreciate the opportunity to come and tell you about my experience with Part D and thank you for passing this bill that has made such a difference in my health and my life.

MR. DEAL. Thank you, Ms. Dennison. Thank you for being here.

MS. DENNISON. If you all would please excuse me, and Mr. Hickerson, we got a plane to catch.

MR. DEAL. I understand that and we are going to get him just as quick as we can. Ms. Capps, I think, wanted to introduce some of the panel here.

MS. CAPPS. I have to apologize very strongly for not being able to stay for this panel and my heart is with you all. Your panel is so important. I had made a previous engagement and I need to leave, but I didn't want to do so without saying a word just to thank Mr. Lipshutz, not just you particularly, but also your volunteers through a program that we call HICAP. California Health Advocates supports it and it is an advocate for health insurance counseling and advocacy programs. Its volunteers are all through the State of California, and they have been lifesavers. We use them every day, 24/7, really, our constituents use them, and they have made a real difference during the implementation of this program and I wanted to mention that, and also the community pharmacists. You are not from my State, but for all the community pharmacists across this country right now, we owe a huge debt of gratitude for getting us through this time.

MS. DENNISON. Ms. Capps, we have a program in Georgia called Georgia Cares.

MS. CAPPS. It makes a difference, doesn't it?

MS. DENNISON. And it has been great.

MR. DEAL. That is fine. Mr. Hickerson, we will recognize you. If you will get the microphone and pull it over there where you can be heard.

MR. HICKERSON. Thank you, Mr. Chairman. Am I coming through?

MR. DEAL. No, you are going to have to push the button.

MR. HICKERSON. Now?

MR. DEAL. Yes.

MR. HICKERSON. Okay, thank you very much, Mr. Chairman, members of the committee. My name is Marcus Hickerson from Waxahacie, Texas, which is in Chairman Barton's district, and I am pleased to have this opportunity to testify today regarding the Medicare Part D prescription drug plan. Today I want to share with you the experience that my wife and I had in choosing our prescription drug plan under Medicare Part D. I have been retired for 17 years from the

petroleum refining and real estate industry and my wife and I have been Medicare Part A and B beneficiaries for 14 years. Let me also add that my wife and I each take four medications on a regular basis. The cost of these medications, the list price on those is approximately $5,000 a year.

Now, after receiving the information on the various drug plans that became available in the fall of 2005, I began comparing Medicare-approved private companies that offered the benefit plans under Part D. My efforts were focused primarily on Internet research of premiums, co-payments, coverage gaps and available drugs covered by plans such as AARP, Medco, Wellcare, United American, Prescription Solutions, Aetna, Humana, and others.

My wife and I have, for a number of years, purchased our prescriptions from Walgreens, which is only a few blocks from our home and Walgreens made available, off of their web site, a compilation of all the drugs that we had purchased over the past number of years, so it was very easy to pull out the drugs that we had purchased for the past 12 months which did, indeed, include the list price of those drugs. So with that schedule, it made it relatively easy to start comparison on the drug sites of the various companies.

I found that the web sites, all of these, some 40-odd plans that were available to those of us in our area of Texas. It was a useful resource and the information allowed me to reasonably compare the formulary of each plan and plan the best match for our needs. Although I invested a considerable amount of time in reviewing the requirements and benefits associated with each plan, I felt satisfied that I had accessed all the information I needed to make an informed decision. As far as the research that I put in, I probably invested some 15 to 20 hours of Internet time over what perhaps was a two to three week period in making my review.

It is important to note that we did not select a plan that did not cover the $250 deductible. In the end, my wife and I selected two different plans that would best fit our individual medication needs. I estimate that we will receive joint annual savings of approximately $2,400 a year off of the list price that were shown in the Walgreen printout. That $200 a month will come in very nice as far as our overall budget is concerned.

Now, finally, I would like to say that there are two important things that I would like to share with this committee as far as the program is concerned. I feel that the key to this new initiative, of course, is choice. As you can see, from my experience, the options available for my wife and I to select a specific plan that best fit each of our unique medication needs was available with a reasonable amount of research. Of course, one size does certainly not fit all, and that was the case that we found.

Now, secondly, I would urge all of the seniors who are eligible, to sign up in this plan. Before they pick a plan, I would encourage them to take advantage of the information and resources available to shop around for a plan that best fits their healthcare needs. Just like shopping for the best rate on homeowners insurance, mortgages or any other item that we purchase, the process of selecting a plan is not unlike those that we face every day. Do I have any complaints? Absolutely none. Do I have a concern? Yes, I have a concern. Levitra is included in my formulary. Now, at age 79 I have a concern because my plan allows for a monthly supply of Levitra to be purchased for a co-payment of $15. My concern, of course, is that that monthly quota is only four tablets. Now, at 79, I will wait for another several months before I decide if my concern becomes a complaint. Thank you, Mr. Chairman. It is good to be with you today.

[The prepared statement of Marcus Hickerson follows:]

PREPARED STATEMENT OF MARCUS HICKERSON

Good afternoon, Chairman Deal and members of the Committee, my name is Marcus Hickerson from Waxahachie, Texas, which is in Chairman Barton's District, and I am pleased to have the opportunity to testify before you today regarding the Medicare Part - D prescription drug benefit.

Today, I want to share with you the experience that my wife and I had choosing our prescription drug plan under the new Medicare Part-D program. First, I have been retired for 17 years from the petroleum refining industry and my wife and I have been Medicare Part-A and Part-B beneficiaries for 14 years. Let me also add that both my wife and I currently take four medications each. We spend approximately $5,000 (list price) a year on these medications.

After receiving initial information from different drug plans in the fall of 2005, I began comparing Medicare-approved private companies that offered by new Medicare Part-D plans in my area.

My efforts were focused on internet research of premiums, co-payments, coverage gaps and available drugs covered by plans such as AARP, Medco, Wellcare, United American, Prescription Solutions, Aetna and several others.

My wife and I currently fill our prescriptions at Walgreens. Because we fill all our prescriptions at Walgreens it was very easy for us to compile the list of our respective medications. It was very important to have this list of medications because that became a key ingredient to selecting the right Medicare part-D plan. Also, by looking on the Walgreens website I was able to compare the prices we paid for these medications, which made it very simple to see how much we would be saving with Medicare.

I found each company website a usehl resource of information that allowed me to reasonably compare the formulary of each plan and find the best match for both our needs. Although I invested a considerable amount of time reviewing the requirements and benefits associated with each plan, I felt satisfied that I had access to all the information I needed to make an informed decision on the plans we selected.

It is important to note that we did not select a plan that did not cover the annual $250 deductible. In the end, my wife and I selected two different companies that would best fit our individual medication needs. I estimate that we will receive a joint annual savings of approximately $2400 off list price.

Finally, there are two important points that I want to share with the Committee and with other program eligible seniors. First, I feel that the key to this new initiative is choice - as you can see from my experience the options available allowed my wife and I to select a specific plan that best fit each of our unique medication needs. One size does not fit all and in our case that was certainly true.

Secondly, by comparing the specifics of what each plan offered I was literally able to shop on-line and select the plan that best met our requirements. Before seniors pick a plan I encourage them to take advantage of the information and resources available and shop around for a plan that best fits their healthcare needs. Just like shopping for the best rate on homeowners insurance or on a mortgage, the process of selecting a plan is not unlike any purchase we have made throughout our lives.

Thank you Mr. Chairman. I am pleased to respond to any questions that you and the other Committee Members may have.

MR. DEAL. Thank you very much and we do understand that you both have to leave. We thank you again for your testimony here today. Anyone else on the panel that is under a real time press?

CHAIRMAN BARTON. Mr. Chairman, could I just?

MR. DEAL. Yes.

CHAIRMAN BARTON. I want to have the privilege to thank Mr. Hickerson. He has been a long-time civic leader in the Waxahachie area and has been very friendly to me over the years. I did not know that he was going to be a witness until he had already been asked to be a witness and after the fact, I was asked if it was okay that he had been asked. I don't want the Members, my friends on the Democrat side, to think we planted him. I didn't know about him until after he had already been approved and said he would testify, but I do appreciate him coming up from Waxahachie. He has done more to help Waxahachie than almost anybody else in Waxahachie and I think he is a former Citizen of the Year. I just went to the chamber banquet and I think I saw your name on that, so we do appreciate you coming and waiting while we saw Dr. McClellan's testimony and then asked him questions.

MR. HICKERSON. Joe, thank you very much and we are proud to be here to be our representative in Washington.

CHAIRMAN BARTON. Well, I am glad that you are having a positive experience with your program. Do you think the average senior would go through the time that you went through to pick a plan? Is that a valid criticism?

MR. HICKERSON. I certainly would hope so. And there were occasions when there were organizations in Waxahachie, including Walgreens, where you could take your medical records down or the drugs that you use regularly and have a consultation with which of those plans fit their needs. But I am sorry to say that not too many people use that information, and I did ask the Walgreen manager how many had taken advantage. He told me out of our community of 25,000 and county population of about 130,000, that only 200 had requested that assistance.

So I think there may be, on the part of a lot of our seniors, just some indication that they are not terribly concerned about their needs for this coverage.

CHAIRMAN BARTON. Well, thank you, sir, for coming.

MR. HICKERSON. Good being with you.

CHAIRMAN BARTON. Thank you, Mr. Chairman.

MR. DEAL. Yes, sir. Thank you, Mr. Hickerson. Mr. Song has indicated that he might also have a time constraint. If the rest of you will indulge us, we will go to his testimony next.

MR. SONG. Thank you, Mr. Chairman. Chairman Barton and Chairman Deal, thank you for allowing me to, and the fellow committee members, thank you for allowing me to share my real life personal experiences. I was listening to Member Bilirakis and he had made a point that he said that we should approach this with an open mind and I believe he said a willingness to learn, and that is how I approach everything. If you note in my testimony, I own Flower Mound Herbal Pharmacy, so I deal on the alternative side. And I wish Dr. McClellan was here because vitamins can improve your health, and they actually can reduce drug costs and I can prove that every day. But I had been a chain pharmacist for over 20 years. March the 8th, which is next week, I will celebrate my eighth year as an independent pharmacy owner. I am a member of the National Community Pharmacist Association and Texas Pharmacy Association and a graduate of the University of Texas at Austin.

To tell you a little bit about myself, my pharmacy is like most family owned pharmacies. I employ 11 employees. I have over nearly 40,000 patients that come to the pharmacy for their medicines, their dietary herbal supplements, and their flu shots. We give 6,000 to 8,000 flu shots per year. In fact, we give more than the county health department. And I supply a lot of the physicians with their immunizations, too. I also give advice about the medicines and dietary supplements. I give talks, in-services to school nurses, county health departments, physicians' offices, and kind of established myself as the central prescription drug and healthcare information center for the community.

One of the things I do that I specialize in is compounding or custom prescriptions and I want to share just a real anecdote. I make a lot of prescriptions for pets and you wouldn't believe what some of the pets, some of the conditions they have. They have conditions like we do; high blood pressure, high cholesterol, anxiety, depression, psychoses. I made a preparation for a cat with anxiety that the veterinarian could not get the cat to take this preparation, so what I did was I went to Sam's, bought StarKist tuna, drained off the water, dissolved the medication in the tuna and the cat loved it.

As far as Medicare Part D, I took steps above and beyond to prepare myself and my staff and also the other pharmacists in my community. I am the president of the Denton County Pharmacy Association, which is the county association. I have been that for the last 12 years. So what I did personally is I hosted an NCPA-sponsored Medicare Part D CE program for two hours. I required all my staff to listen to a teleconference, an hour teleconference. We had staff meetings, and we kind of established ourselves as the point pharmacy in our community for Medicare Part D questions. Even with all that, I also made presentations, and I continue to make presentations, to Rotary Clubs, to senior groups, and to hospital groups. Even with that preparation, the first two months of this program have been very difficult for me and my patients.

As a small business owner, it has been a struggle. The problems are pretty well documented. Primarily, the transfer of information of CMS to the different health plans; there have been a lot of problems with the dual eligibles. Dr. Burgess called me about two weeks after it implemented, about the second week in January and truthfully, anyone that knows me knows that I will speak the truth and I will be very upfront and very blunt sometimes, and the first thing that comes out of my mouth is well, it hasn't been that bad. Then I realized I only have two dual eligible patients that use me. When they came in, both of them didn't work. One was because they weren't enrolled properly, because information was transferred improperly. And the other part was our State is undergoing another transition, too. They are handing their processing of their prescriptions to a private plan, health plans and there has been delay of payment there, also.

In fact, one of the pharmacies in Victoria, he owns five pharmacies, he has an outstanding debt of $170,000 right now that he has been going into. But I answered Dr. Burgess and I said for me, personally, it hasn't been that bad, but then I realized I haven't really been exposed to that many of the seniors and it is because what I realize, and my problems really started the end of January and this month, is because the seniors stocked up at the very end of the year because they were anticipating some problems, so they didn't get their refills until just a few weeks ago and now is where we are experiencing the problems because we are seeing those recipients come in with their new cards or their new letters.

To give you an example, I have about 50 plans in my region and Mr. Hickerson talked about choice and I believe there is choice, this is a free enterprise system, but for an independent pharmacist there is no choice. There are 50 plans in my area, I have to enroll in every single one of them and hope that the reimbursement is enough to cover my cost, which a lot of plans, they are. I can be exclusionary, but then I lose my

patients, so there is no choice for independent pharmacists. We have to accept every plan that is out there. And the contracts are not negotiable. Regardless of what they say, we cannot line item, we cannot change anything. We accept it or we reject it as is.

I have two pharmacists. One has a retired father that is a pharmacist in Birmingham, Alabama and they went on the web site. It took them four hours and they did finally wade through it, but it took two pharmacists, a retired pharmacist and a practicing pharmacist, to wade through the web site. Sometimes the problems we have been experiencing lately are the hold times. Even though they have gotten better, we still experience hold times. The plan help desks are still overloaded. We have, in the past, gotten false rejection codes saying member not on file, pharmacy not participating. It really turned out to be a wrong date of birth, maybe a wrong ID number. Since then, that slowly had been corrected. The prescription claims are going through, like I had mentioned, the wait time has decreased, but you know, I don't think it is fair to the Medicare recipients or the community pharmacists to have up to sometimes one hour wait times, especially when you are doing 100 to 200 prescriptions a day, which is a fairly low volume for a pharmacy.

There has been some dialog between NCPA and CMS, and if Dr. McClellan was here, I would say thank you and especially to Secretary Leavitt who said all of our, as far as community pharmacists, our efforts were heroic. We are not heroes. We are very, very compassionate. We are healthcare providers and the patient is the utmost, the beneficiary is the utmost important, or the most important person. One of the things I have done is I have tried to, I have given CE programs to physicians' practices and nurse practitioners, this was the two a couple of years ago when the prior authorization process really rolled in, to try to explain the managed care prior authorization process and I always try to approach everything objectively. I don't try to blame anybody. That doesn't win in any case.

But I have trouble now trying to explain objectively why their medications are being switched, or why they are being solicited to being therapeutically switched and is it due to the rebates? Is it in their best interest? The PNT committees Dr. McClellan talked about, who are they comprised of and do they know the specifics of that physician's patient and is that the best medication for them? There are a lot of drugs in a therapeutic class, but each one has side effects inherent in characteristics to each drug, so I believe it is up to the physician, along with the work with the pharmacist, to select the drug that is most appropriate and safest for that patient.

Real quickly, I am going to wrap up by saying that I would like to share with you a couple stories. I have had one patient that, in the Dallas morning news about two weeks ago, maybe three weeks ago, there was a statement from Secretary Leavitt saying that, and it was repeated by Dr. McClellan as saying our patients should not leave the pharmacy counters without their prescriptions. The pharmacists have tools to ensure that. Well, he was a newly diagnosed diabetic. He had just gotten over the shock of being diabetic, being diagnosed diabetic, had to buy strips, a blood glucose monitor, and he didn't want to do that.

Then it came to his medications. His plan said he paid $8.50. Well, he wasn't enrolled in his plan because of some mis-transfer of information. So after trying to explain to this patient, a newly diagnosed diabetic, that I couldn't submit his prescription. By the way, that is how a prescription is adjudicated or a claim is submitted, simultaneously at the time that you fill a prescription. So it is either make the patient wait, or you give them the prescription. Anyway, he brought this news article to me, circled it, and he said, you know, they said that you would take care of me, you wouldn't let me leave. So there were a couple things, because I had no confirmation, I didn't even know what process or what plan he was on. He knew he had it, he knew he submitted it, but what I basically did is I gave him, for his co-pay, and tried to explain to him, for the $8.50, this is out of my pocket, $18. And hopefully, we will get it resolved. Hopefully, the next time you come in it will be covered under your plan.

The other one was a friend of mine and for the sake of time, and I don't want to take away from any of the other participants, but we call ourselves family pharmacists because, you know, all our patients are our family and that is a big distinction of the independent pharmacist. When she knew, after countless hours of trying to wade through which plan is best for that patient, so after countless frustrating hours of trying to select the best plan for her, and she was on at least eight different medications. She was a breast cancer survivor and she has been my patient for over 20 years, so she is very near and dear to me and we have a very candid and a very close relationship. After hours of trying to figure out the best plan and not finding one out, she told me three things and I would like to leave with this, and I wish Dr. McClellan was here. She told me thank you, you are doing your best, and please don't let us seniors down.

With that, the rest of my testimony, I think you have copies of, but in conclusion, I would just like to say I love being a pharmacist. Most pharmacists are in this profession because we love taking care of people. Even despite we want this Medicare system, we know it is a benefit, we want it to work. Dr. Burgess was kind enough to outline the concerns

that we have and we are here to help you try to make this work. Thank you.

[The prepared statement of Dennis Song follows:]

PREPARED STATEMENT OF DENNIS SONG, FLOWER MOUND HERBAL PHARMACY, ON BEHALF OF NATIONAL COMMUNITY PHARMACIST ASSOCIATION

Good Morning, Chairman Barton, Representative Deal, and members of the committee. Thank you for conducting this hearing and for providing me the opportunity to share the experiences with the new Medicare Part D program on behalf of the more than 24,000 community pharmacies and their patients.

My name is Dennis Song and my family pharmacy is Flower Mound Herbal Pharmacy in the Dallas-Ft. Worth Metroplex. I have worked in chain pharmacy for the first 20 years of my career and have owned my pharmacy for 8 years. I am a member of the Texas Pharmacy Association, the National Community Pharmacists Association, and a graduate of the University of Texas.

My pharmacy is like most family owned pharmacies....it employs 11 employees and have nearly 40,000 patients that come to the pharmacy for their medicine, dietary supplements, their flu shots, and for advice about their medicine. I also have many doctors, school nurses, and the county health department that utilize my pharmacy for drug and healthcare information. In a sense my pharmacy acts as the central medication information center for my community.

I make customized medications for patient's pets. For example, just last Tuesday I made a cat anxiety medicine and drained tuna cans to give it a tuna flavor. I deliver prescriptions to my patient's home if they want me to and I open after hours when patients need their medicine.

Like most every other pharmacist I know, I prepared for the Medicare Part D benefit by reading as much as I could and going to programs. I required my staff to attend educational programs and teleconferences to make sure they were prepared to help patients. I also gave Medicare Part D talks to the Rotary Club, senior and hospital groups. Despite my preparation, the first two months of the program have been very difficult for me as a small business owner and, most importantly, a struggle for my patients.

The problems have been well documented—there were problems with the transfer of patient information between CMS and plans, there were early problems with the eligibility inquiry system, and there was a lot of confusion among dual eligibles and other senior patients about which plan they were on and what they needed to do to navigate the system. At our pharmacy—and in thousands of others across the country—we did what we could to help patients. There are about 50 plans in my region but we tried to answer as many questions about plans as we could. Two of the pharmacists that work for me spent hours on the Medicare website trying to help their parents get enrolled. If it takes a pharmacist a couple of hours to enroll, there's no way an elderly patient should be expected to go through a website. Plus, I could count on one hand all of my senior patients who have a computer. Factor in the indigent, the dual eligibles, and its not surprising there was so much confusion.

We called plans and were on hold sometimes for close to an hour before we finally gave up. We did our best to make sure that patients were able to stay on their medication while we worked through the insurance hassles by giving them emergency supplies of their prescriptions. During the first couple of weeks, we gave an emergency supply to 20 percent of the elderly patients who came in the pharmacy—we want to make sure our patient's don't do without. Last, but not least, we opened up a line of credit at the bank so we could pay our bills but I'll talk more about that a little later.

Things have improved in the last few weeks but there are still huge problems for the patients that will continue if needed changes to the program are not addressed. Prescription claims are going through much more often than they were but there are still quite a few that are rejected as unpaid—especially at the first of the month. The wait times on the phone have decreased but they are still running 5-10 minutes per call—but much better than an hour. When you are trying to fill two hundred prescriptions a day, it makes for an unacceptable situation for the pharmacy and for the patient.

My national association, NCPA has told me that there is an ongoing dialogue between CMS staff and the pharmacies and the CMS advisement increasing the time for transitional fills to 90 days has helped delay the problems that patients will have when the plan formularies are enforced. However, I do worry about patients when those formularies kick in. The pharmacists will have to try to explain to patients and their caregivers that the blue pill for their heart that they have been taking for years has been switched to a yellow pill that should do the same thing. That creates serious confusion and frustration for seniors. On top of that, I always ask myself if that is the best medicine for my patient. Plans change their formularies all the time depending on who is giving them the biggest rebate. It concerns me that patients might get confused or just fed up and stop taking their medicine.

As I mentioned, we try to make sure our patients don't have to do without their medicine. As an example, I had a newly diagnosed diabetes patient who came in with the front page of the Dallas Morning News quoting Secretary Leavitt saying that "no patient should leave the pharmacy without their prescription." He had actually circled the quote. He had enrolled in the plan but the plan had not entered him into his system. We tried to explain the situation to the patient but he kept referring to the newspaper quote. I wound up selling the medicine to him for what his co-pay *should* have been which was $18 below my cost. What made it even worse was that there were two other patients—one who was another Medicare patient--who walked in and walked out because I was too busy trying to help the Medicare patient.

I mentioned the line of credit I opened so my pharmacy could pay its bills. One of the big problems with Medicare Part D is that the payments from the plans are slower and lower. By slower, I mean that for the dual eligibles, we used to receive payments from the state Medicaid program every 7 days. Under the new program, we are only supposed to get paid every 2 to 4 weeks but I have to pay my wholesaler bill weekly.

The plans make it difficult to tell what prescriptions have been submitted and what have been paid for. Some of the larger plans have also found reasons to delay payment. The point of the program is not for the plans to make money on the float but for me, it's made cash flow tight. I've been in business for 8 years and for the first time I've had to open a line of credit. I've almost maxed out the line and now I'm afraid my next move is to go into personal savings to try to cover the costs. It's scary. I know of a few pharmacies like mine that have already gone out of business over in the Valley in South Texas and I think there will be many others that will also have to close their doors if some changes to the program aren't made. Why are we being asked to both serve patients on the front lines and be the bank for the program? Unlike banks we collect zero interest for the money we are being forced to provide loans.

Some of the changes that I think should be made to the program are:

1) *There needs to be a prompt pay provision.*

Electronic Fund Transfers are done everyday with credit cards and banks. There is no reason why Plans couldn't pay the pharmacy on a daily basis or at least on a weekly basis. Pharmacies have no ability to negotiate with the plans—the contracts are take it or leave it—so we need CMS to step in and tell plans that they must pay the pharmacies with a daily EFT.

2) *The prescription cards that the plans issue should not be allowed to have a company specific logo on it.*

For example, one plan puts the Wal-Mart logo on their card. That seems outrageous to me and will make some patients think they have to switch pharmacies. Pharmacists are strictly prohibited from steering patients but the logo of a chain pharmacy is allowed on a card? Again, we need CMS to tell the plans—not just recommend--that they can't put a pharmacy logo on a patient's prescription card or there needs to be legislation to correct this situation.

Pull out your social security card. Is there an advertisement on that card? There should not be any advertising that serves as proof of admission to Medicare Part D. This is a clear violation of the anti-steering provisions spelled out in the marketing guidelines issued by CMS.

3) *Patients, doctors, and pharmacies need a standardized method of dealing with the plan formulary issues.*

Right now, if a prescription is not covered, a lot of plans send the pharmacy a message that says "drug not covered". That's it. No explanation as to why it was not covered. So, the pharmacy has to call the plan and find out why the drug is not paid for and what needs to happen to help the patient get their medication. The pharmacist then has to coordinate the paperwork between the patient, the doctor, and the pharmacy in order to help the patient get their medicine. This can take hours or even days. After all that time, the patient hopefully has not given up on the process and decided not to take their medicine.

There needs to be standardized messaging between all of the plans when they communicate with pharmacies and a standardized prior authorization procedure that reduces the administrative burden on patients, doctors, and pharmacies.

4) *Enrollment period needs to be realistic*

Patients were told that they could enroll as late as the end of the month and be in the system by the next day. That doesn't happen and is not a realistic expectation by anyone in the system. The result is that beneficiaries are frustrated and pharmacy staff have to chase down claims to try to help get the prescription paid. This unrealistic expectation creates a chain reaction that upsets the entire benefit. Dual eligible patients should have a deadline of at least 15 days and non-dual eligibles should have at least 30 days to be entered into the system.

5) *Standardized Contract Rate*

Pharmacies have dozens of plans offering take it or leave it contracts. Family owned pharmacies have no ability to engage in any form of legitimate negotiations. As a result we are forced to sign contracts that reimburse us below our cost. We believe CMS should use its authority to provide reimbursement guidelines to plans or there needs to be legislation to address the situation so that pharmacies are able to stay in business and continue to provide the services I have described here today for the American public.

In conclusion, I would add that I enjoy being a pharmacist and I believe I am making a difference in the thousands of patients who come in my pharmacies. However, I am very concerned that the slower and lower Medicare payments this year on top of the massive Medicaid cuts that Congress passed last month will force thousands of family

pharmacies to go out of business and strand millions of patients without access to the medicine they need to help them stay healthy.

Thank you again for inviting me to share my experiences with the Medicare Part D program with you.

MR. DEAL. Thank you, Mr. Song. We appreciate what you do and please convey to your members of your association our appreciation for what they have done to try to get over these rough spots and I think it will get better. Mr. Paul, we are going to go to you next and then we will come back down the line.

MR. PAUL. Thank you, Chairman Deal and other distinguished members of the Health Subcommittee and honored guests, for the opportunity to testify before you today about the implementation of the new Medicare Part D benefit. My name is Tom Paul and I am a pharmacist and the Chief Pharmacy Officer for Ovations, a United Health Group business that focuses all its attention on individuals 50 and older. That population is the primary users of the Medicare and Medicaid program. Our participation in these programs is really fundamental to our core mission and that is to facilitate broad and direct access to affordable, high-quality health care that helps individuals, families and communities to improve their health and well-being.

Implementing Medicare Part D was and is an enormous and ambitious endeavor. Clearly, in its early stages the program has experienced major shortcomings. These shortcomings are a major concern for all of us, which is why we are here today. I would like to provide you with a brief overview of our company's efforts around Part D, and our efforts to resolve some of these initial challenges. I encourage you to reference my written testimony for further detail.

I am pleased to report that through coordinated efforts of many, we have seen the beneficiary experience dramatically improve, especially in comparison to the first weeks when the program began. Through Part D, many beneficiaries are receiving prescription drug coverage for the first time. Millions of seniors are seeing real savings on each prescription they purchase in comparison to prior to January 1st. Moreover, Part D coverage is providing millions of other beneficiaries a safety net in case they need to use prescription drug benefits in the future.

Nonetheless, much remains to be done to make sure the program works successfully for all beneficiaries and most importantly, that those who need the coverage most are signing up. We are committed to make sure that the system works as it should for every beneficiary. I should note that tremendous preparation went into launching the program. Ovations put significant efforts and resources into technology, enhanced pharmacist information and support and expansion of and training within our call centers, and customer service sites.

Well before January we recognized the need for consumer education and we launched a broad national consumer program around Part D. This outreach included events across the country, dissemination of 10 million consumer booklets in multiple languages, and other initiatives specifically targeting the low-income population. This outreach was intended to ensure that eligible individuals would understand their options and know how to access and make full use of the new drug benefit program that was available to them under Medicare. That said, as Part D launched, it became very clear that the program was not working as well for all beneficiaries. Specific problems were caused by incomplete, inaccurate enrollment and eligibility information received by the health plans, including delays and that data transfer between CMS, the health plans, and pharmacies.

Also, a large number of late month enrollments and switches from one plan to another by duals and other low-income beneficiaries caused some of the challenges that we experienced. These challenges in determining eligibility led to difficulties locating enrollees in the system when they came to the pharmacy. It may have led to temporary classifications in the standard benefit plan to ensure that there was some level of coverage for beneficiaries, but it may have resulted in co-payments that were higher than expected by that beneficiary. All of this resulted in an unanticipated surge in call volumes, creating significant delays in response to both consumers and the pharmacists.

As these challenges arose, we quickly reacted to address them. Everything we have done has been geared to making sure that no one leaves the pharmacy without the prescription drugs that they need. Ovations is doing everything possible to help ensure that these beneficiaries receive the assistance promised under the Part D program. More specifically, we worked on multiple fronts to ease the transition of enrollees and resolve the enrollment and information technology system issues. We have been working aggressively with CMS, States, pharmacists, and other partners to ensure that the root cause issues of inaccurate and untimely eligibility are being resolved.

We have taken numerous steps to ensure that low-income and other beneficiaries have immediate access to their Part D benefit, but also that pharmacists are in a position to help these enrollees. My written testimony details these steps which range from rapid improvements in our call center operations and significantly enhancing pharmacist support to developing temporary solutions to meet the needs of low-income beneficiaries while longer term problems are being resolved.

We continue to see steady improvements across the board. Today United Health Group's Medicare Part D programs are largely working as intended for those recipients accessing the program. More than 4.5

million Medicare beneficiaries are successfully using the stand-alone and Medicare Advantage prescription drug plans today under United's programs. More than 60 percent of them are non-duals who voluntarily enrolled in the Part D program. On average, we are filling more than eight million prescriptions in each month that we have had the program in operation.

A very low percentage of claims are now being delayed at the point of sale as the eligibility and enrollment issues have been resolved. This means more and more beneficiaries are receiving their ID cards in a timely manner. Complete billing information is being submitted to their plan and the pharmacists are getting access to the information that they need to make the prescription dispensed at the point of service. Finally, call volumes are down and call wait times have vastly improved since the program began.

Ultimately, though, the prescription drug program is really not about an individual plan, it is about the people. And you have heard testimony today from Ms. Dennison and Mr. Hickerson, but we also have one person we would like to highlight, Fran Cooper, from Bellevue, Nebraska. She actually had no intention of joining the Part D plan and she actually called us to make that known and to tell us why. She was very opposed to the plan and what it meant, and the challenges she would face with it. After we talked through the program with her and her concerns, I am happy to say that she has enrolled in a program. She is using that program and she is now an advocate for others, telling them of the value that this program could mean to them.

But just the fact that we have heard from these three individuals and others that we have heard about today won't satisfy us until the program works for all beneficiaries that need this important benefit. We continue to work with CMS toward resolving the enrollment and eligibility and data issues with the States to address any remaining issues that remain for the dual eligibles. We also are working with pharmacists to identify ways to further ease the transition to Part D. You heard that from Dr. McClellan about plans that are working with the pharmacy associations in order to make their lives easier through things that we can do via standardization of the program.

We have intensified our education outreach effort to make sure that we are reaching those that need to hear more information about the program. We can't overstate the importance of reaching out to the lower income populations, particularly those not eligible for Medicaid, to understand the value that they will receive under Part D. It is important to answer their questions and remove any barriers to their participation in the program, and we encourage others to undertake similar efforts. More effectively managing the beneficiaries' expectations around enrollment

and formularies is a key part of this. Dr. McClellan also spoke of this. We appreciate the efforts of CMS and Members of Congress to encourage beneficiaries to enroll or switch plans early in the month. This will help ensure enrollment is completed by the first of the following month.

Part D is an ambitious and valuable program that is helping millions of individuals on a daily basis to purchase the prescription drugs that they need. This includes many who have previously not had access to drug coverage, and many more who would not qualified for greater assistance through other Federal or State programs, including Medicaid. United Health Group remains committed to working with you, CMS, States, pharmacists, and beneficiaries to ensure that Part D is working for all enrollees, especially those who have found the transition to Part D difficult. We especially appreciate the committee's leadership in this important matter and thank you for the opportunity to share our thoughts. I would be happy to answer any questions that you might have at the appropriate time.

[The prepared statement of Tom Paul follows:]

PREPARED STATEMENT OF TOM PAUL, CHIEF PHARMACY OFFICER FOR OVATIONS, UNITED HEALTH GROUP

Introduction

Thank you Chairman Deal, other distinguished Members of the Health Sub-committee and Honored Guests for the opportunity to testify before you at today's hearing about the implementation of the new Medicare Part D drug benefit.

My name is Tom Paul and I am Chief Pharmacy Officer, UnitedHealth Group/Ovations. Ovations is UnitedHealth Group's business that focuses on meeting the healthcare needs of the over-50 population – the very group of Americans who are the primary users of Medicare. Ovations and the other companies of UnitedHealth Group have extensive experience providing health care services to the federal government, state governments and private payers in many types of competitive environments.

Our company has a long-standing commitment to enhancing health care for older Americans and other Medicare beneficiaries. We are dedicated to helping them address needs for preventive and acute health care services, manage chronic conditions and respond to unique and often complex health and well-being issues. Through Ovations and the rest of our family of businesses, UnitedHealth Group provides the most comprehensive array of health and well-being services to these populations. We are a major provider of services through the traditional Medicare fee-for-service program, health plans, and demonstration projects for the frailest beneficiaries of Medicare. Together with PacifiCare, we are proud to be one of a handful of companies to offer Prescription Drug Plans in all 50 states.

Our participation in Medicare programs is fundamental to our core mission: to facilitate broad and direct access to affordable, high quality health care helping individuals, families, and communities to improve their health and well-being. Our commitment is therefore to the beneficiaries, the programs and the taxpayers who support them, rather than to a specific product offering.

With this in mind, we believe we can offer a valuable perspective on the new prescription drug benefit and appreciate the opportunity to testify before this Committee and to share our experience to date with its implementation.

Early Challenges

Medicare Part D is the most significant change in the Medicare program since its enactment more than 40 years ago. Implementing a program of such unprecedented size and scale is an enormous and ambitious endeavor – and as we all know, Part D has experienced some challenges in its early stages. We should note though that the Part D benefit is currently serving the majority of beneficiaries well. As the Centers for Medicare & Medicaid Services (CMS) has reported, Medicare Part D plans overall are now contributing to the well-being of more than 25 million beneficiaries as of February 22nd, including more than 5.3 million beneficiaries who have signed up individually for prescription drug coverage.

However, we are as concerned as all of you that the system has in some cases not worked well for all beneficiaries. This is especially true for a minority of low-income and dually eligible enrollees, largely due to unanticipated information gaps in the system. Information on eligibility was not available to pharmacies for certain duals and other low-income beneficiaries in the way it should have been. This was due to:

- Incomplete enrollment and eligibility information received by the health plans and delays in its transfer among CMS, health plans and pharmacies; and
- Late-month enrollments and switches from one plan to another by duals and other low-income beneficiaries leading to delays in posting eligibility information in the system.
    - For example, in the latter half of December, immediately prior to the January 1 program start date, we were receiving approximately 75,000 applications per day.

The resulting challenges in determining eligibility led to people not being found in the system or their temporary classification in a standard low-income coverage tier, making their initial co-payments higher than expected. It also resulted in an unanticipated surge in call volumes, creating delays in response to both consumers and pharmacists.

Responding to the Challenges

Since these challenges first came to light at the beginning of this year, our company has taken quick action on multiple fronts to help enrollees and pharmacists and resolve the situation, especially as it affects dual eligibles and other low-income individuals. We have done, and are continuing to do everything we can to work with CMS, states, pharmacies, and other partners to help resolve outstanding enrollment and information technology system issues.

Parallel to this, Ovations has taken proactive steps to ensure as smooth a transition as possible for our enrollees and pharmacists – from making rapid improvements in call center operations and enhancing pharmacist support, to developing temporary solutions to meet the needs of low-income beneficiaries while longer-term problems are being resolved. Among the steps we have taken are the following:

- We acted quickly to ensure low-income and other beneficiaries would have immediate access to their Part D benefit regardless of whether they appeared immediately in the system, by:
    - Activating a beneficiary's plan coverage by "assuming" or "deeming" an individual's enrollment even before receiving confirmation of enrollment from CMS, where possible;
    - Assigning beneficiaries to a subsidized co-payment class even in advance of a CMS confirmation;

- Implementing in coordination with CMS a temporary "first fill" and transition plan process that permits new enrollees access to Part D covered drugs on an expedited basis;
- Making administrative adjustments, such as changing the medication supply window from 30 to 31 days to assist with claims processing from Long Term Care pharmacies serving institutionalized beneficiaries;
- Conducting outreach to beneficiaries whose enrollment may not have been confirmed by CMS in time for the 1st of the month start date (e.g., because they enrolled or switched plans late in the month) and advising them on how best to access their benefits early in the month; and
- Lifting on a temporary basis prior authorization and step edit requirements on almost all medications in order to give pharmacists and enrollees ample time to adjust to their new Part D plans. We retained prior authorization on four drugs for which our Pharmacy & Therapeutics Committee has special safety concerns for older adults.

- As I said, at the end of December, Ovations was receiving approximately 75,000 applications a day, and enrollment remains strong, with thousands of applications continuing to come in each day.
- In order to meet the continued strong demand for our program and ensure high levels of service, we have increased our call center staff significantly.
  - We now have more than 3,600 employees deployed at our seven call centers and continue to increase personnel and improve performance in our call center operations so that issues can be resolved "real time."
  - We immediately established a "hotline" with CMS in the first week of January for their case workers to escalate enrollee cases and are in constant communication with CMS to assist beneficiaries.
  - We also established a similar "hotline" for AARP.
  - Work is also underway to add two additional call centers to ensure continued high levels of service, with representatives in these call centers to be phased in over the next two to three months as they complete training.
  - I should note that our customer service representatives receive extensive ongoing training and daily updates highlighting important issues and how to resolve them.
- We also expeditiously took steps to ensure that the system works more efficiently for pharmacists:
  - We have more than doubled the number of representatives available to assist pharmacists since January 1st.
  - We established a direct hotline for pharmacists to escalate and triage issues with enrollees, or finalize enrollment if there were application issues – all on the spot where feasible.
  - We are providing up-to-date information and support to pharmacists participating in the program – if necessary, on a near-daily basis.
- Finally, we are working closely with CMS to identify and address information gaps and to facilitate reimbursement to states for Part D costs they have borne for low-income recipients.

On that last point, I want to express our deep appreciation for the steps being taken by the states to help address gaps in coverage for low-income beneficiaries. We are committed to seeing that the states are reimbursed in a fair and timely manner for prescription drugs covered by Medicare Part D.

The Results

I am pleased to report that through the coordinated efforts of many, the program is functioning much better today than in the early weeks of January. I am deeply

encouraged by the stories I hear every day about people receiving prescription drug coverage for the first time and about seniors who are keeping more money in their pockets through the cost savings realized under their new Medicare Part D Plan. Simply put: the Part D program is delivering real savings to seniors.

At the same time, Part D coverage is providing seniors and others eligible for Medicare with a safety net in case they ever would need it. The knowledge that they will be protected if their situations change and their drugs costs rise offers Part D beneficiaries some peace of mind – a truly valuable benefit for older Americans and their families.

By all the data and enrollee accounts, UnitedHealth Group's Medicare Part D programs are working as intended for most recipients and we continue to see improvement across the board on a steady basis.

- Just two months into the program, we at UnitedHealth Group are proud to report that more than 4.5 million Medicare beneficiaries have enrolled in and are successfully using our stand-alone *and* Medicare Advantage Prescription Drug Plans.
    - About 40% are individuals dually eligible for Medicare and Medicaid (so-called "duals" or "dual eligibles") and other low-income beneficiaries eligible for a full low-income subsidy.
    - This means, in turn, that approximately 60% of our enrollees are non-duals and voluntarily enrolled in programs offered by UnitedHealth Group.
    - Of our duals, nearly a quarter or 25% of these beneficiaries actively selected and enrolled in a Part D program offered by UnitedHealth Group.
- More than 8 million prescriptions are being filled on average through our plans on a monthly basis by duals and non-duals.
- Eligibility and enrollment issues at the pharmacy are no longer a significant issue, as demonstrated by the very low percentage of claims transactions not making it through the system due to eligibility or enrollment problems.
- Call volumes are down and call wait times are vastly improved for both beneficiaries and pharmacists since the start of the benefit and even since the beginning of February.
- Enrollment response times from CMS have improved considerably.
    - This means more and more beneficiaries are receiving their ID cards before their participation in the program begins.
    - It also means that even if a beneficiary forgets his or her card, complete billing information for their plan is available to pharmacists the first time the beneficiary visits the pharmacy.

These are very significant results, which underscore the fact that the Part D benefit is helping to make affordable prescription drug coverage available to millions of seniors and disabled individuals, including those who previously would not have qualified for assistance through other federal or state programs.

How UnitedHealth Group Prepared for Part D

In preparing for the roll-out of Part D and in responding to the initial issues, we invested millions of dollars and hundreds of thousands of hours in technological upgrades, consumer outreach and education, enhanced pharmacist information and support, and expansion of and training in our call centers.

In the course of this preparation, we have been in constant communication and engaged in intense preparation with CMS, state governments, and members of our pharmacy network. As an example of this preparation, well before January, we engaged in a broad national educational campaign about Part D. The goal was to ensure that individuals eligible for the Part D benefit would understand their options and know how to access and make full use of the new prescription drug benefits available to them under Medicare.

As part of this effort, we developed an educational consumer booklet known as the *Show-Me Guide*. We published the *Show-Me Guide* in seven different languages (English, Spanish, Chinese, Russian, Vietnamese, Korean, and Tagalog) and distributed the *Guide* widely to consumers, providers, advocates, and governmental representatives at both the state and federal levels.

We conducted and participated in hundreds of community events nationwide to help people understand Part D. In doing so, we partnered with associations, AARP and other advocacy groups, community organizations, Members of Congress, state and federal agencies, retail pharmacies and employer customers. We developed specialized materials and seminars for low-income populations, pharmacists and doctors, as well as for constituents of organizations such as the National Kidney Foundation, American Association of Homes and Services for the Aging, National Association of Chain Drugstores and the National Hispanic Medical Association.

We also launched two educational websites:

- www.MedicareRxInfoSource.com, in July; and
- In November www.PartDCentral.com – to help families and caregivers of Medicare beneficiaries.

And in the months prior to the enrollment period we made our call centers available to anyone who wanted information about Part D.

In another example of our preparatory steps, drawing on our deep experience with the Medicare population and much additional analysis, Ovations strove to ensure that our formulary was one of the broadest, most open and non-restrictive. Ovations' formulary as we developed it covers 100% of CMS' top 100 volume drugs without requiring prior authorization. It also is one of the few formularies to include all 178 Part D covered drugs that the Health and Human Services' Inspector General reports as most commonly used by dual eligibles. And, the Ovations formulary contains just 39 drugs with prior authorization requirements and five with step therapy requirements. Again, as I said earlier we temporarily suspended these requirements for all but four drugs in order to give pharmacists and enrollees ample time to adjust to their new Part D plans.

Under strict guidelines of the Medicare Modernization Act, all plans must review prior authorization requests as expeditiously as the enrollee's health condition requires, but no later than 72 hours for standard requests. In the rare cases where not taking the drugs could be life-threatening or raise other clinical concerns, we developed a policy of dispensing a five-day supply to ensure patient safety. Consumers can also request an expedited review, which ensures that their claims are resolved within 24 hours. Ovations' practice has always been to only target drugs for prior authorization based on the drug's potential for inappropriate use, safety, cost, and other similar factors.

It's also worth mentioning that:

- We developed the Ovations formulary based on years of experience with senior and complex populations. As a result, historical data suggests that only 0.2% of prescription claims are for drugs that would be subject to prior authorization on the Ovations formulary. Similarly, only 0.5% of claims would be subject to a step therapy edit based on these historical data.
- Ovations does not require prior authorization for common drugs such as those for Alzheimer's disease, and the list of drugs for which Ovations requires prior authorization is well below the industry average.

All of this is important to understanding why, overall, those who enrolled in UnitedHealth Group's plans express a high degree of satisfaction. We are excited by the positive feedback we have been receiving from our enrollees and want to share some of that with you.

Ultimately, the new Medicare Prescription Drug Benefit is about more than any individual plan – it is about the people.

It is about people who, before Part D, had no access to affordable prescription drug coverage. It is about people like Fran Cooper from Bellvue, Nebraska who thought so little of Part D that she wasn't even going to enroll in a plan. In fact, she called our offices just to let us know how much she disliked Part D. We were able to show her how Part D could help her save on her prescription drug costs and make sure she was enrolled in time to begin realizing those savings on January 1st. And, like many of our members, we were able to guide her through some of the hurdles she encountered in the program's opening days.

It is about people like Sarah Blackwell from Auxvasse, Missouri who is now realizing significant savings on her prescription drug costs thanks to the subsidy Part D provides for beneficiaries with lower incomes.

And, it also is about people like Georgina Vigilance from Springfield, Virginia who values the peace of mind that Part D provides to her and her husband. They take only two prescriptions between them, but know that should their health change they will not have to worry that the prescriptions that could save their life will be out of their reach.

Still More to Do

Despite the start-up issues, there is a fair amount of good news to talk about with respect to the Part D program. However, our work to make the program succeed for all beneficiaries and, very importantly, to ensure that those who need it most are signing up is by no means finished. We are resolute in our commitment to help deliver on this promise for all beneficiaries.

To accomplish this we continue to collaborate with CMS to assist the Agency in resolving enrollment and eligibility data issues that are at the heart of the early Part D implementation challenges.

We are also working with pharmacies directly and through our industry trade associations to identify ways to make the transition to Part D easier for pharmacists. For example, as a group, we are currently looking at standardizing across all plans the electronic messaging pharmacists receive to address Part D-related administrative issues (e.g., when a drug is not covered – either because it is a Part D excluded drug or is covered under Medicare Part B).

While the bulk of the enrollment-oriented issues have been addressed – or are in the process of being addressed – we are working with states to ensure that any remaining issues relating to dual eligibles are resolved. We are placing a particular focus on ways to ensure a smooth transition of duals to Part D going forward as they become dually eligible and if and as they switch plans.

In addition, we are working with CMS, community organizations, associations and others to more effectively managed beneficiaries' expectations around enrollment and formulary. On this note, we appreciate the efforts of CMS and Members of Congress to encourage Medicare beneficiaries to enroll early in the month and avoid late-month switches in order to ensure that their enrollment is completed by the 1st of the following month.

As CMS has intensified its educational outreach across the board, we at Ovations are redoubling our outreach efforts to low-income individuals to encourage them to apply for subsidies and to join a Part D plan. For example:

- We recently launched a new community grassroots outreach campaign in ten regions across the country to help educate, inform and enroll beneficiaries, especially low-income individuals.
- Our Evercare division, which serves the frail elderly, chronically ill and disabled, is conducting telephone call-in seminars for beneficiaries who find it hard to get around and busy adult caregivers. The first event will focus on Medicare Part D and give participants the opportunity to ask frank questions and gather unbiased information from a panel of representatives from local and national health

organizations. It will be held on March 10th for participants in Boston and Worcester, Massachusetts and the Houston and Harris County areas in Texas.

We intend to expand these targeted beneficiary education efforts in the coming months and are working with CMS and community-based groups to do so. Since last summer, we have worked with members of the Congressional Black Caucus to reach out to Medicare beneficiaries in the communities they represent. We recently met with leaders of the CBC to discuss ways in which we can intensify this outreach. We also are following-up with those organizations who requested copies of the *Show-Me Guide* for their members, employees, clients or constituents to offer additional educational assistance. Ten million of those guides were distributed in the course of our education campaign.

We would encourage others to do the same. The importance of helping lower-income populations ineligible for Medicaid in particular understand the value of enrolling, of clarifying their misperceptions and questions and of removing barriers for them cannot be underestimated. There are an estimated six to eight million low-income people who should qualify for subsidies under Part D but are not eligible for Medicaid. These are people, who likely have no prescription drug coverage and can, for the first time, save significantly over the retail price for their medication. As noted, almost half of Ovations' members are low-income individuals who may not have had any prescription drug coverage previously.

As we emphasize the importance of encouraging low-income individuals to apply for subsidies and enroll in Part D, we also want to recognize the important work State Health Insurance Assistance Programs (SHIPs) play in this regard. Consequently, we would encourage you to consider increasing the funding made available to support these organizations so that they can help ensure that beneficiaries – especially low-income individuals – are able to easily access the Part D program.

Conclusion

In conclusion, I would like to say that we believe the Medicare prescription drug program is working for the vast majority of beneficiaries. Enrollees in UnitedHealth Group/Ovation's Medicare Part D plans are realizing significant savings and report a high degree of satisfaction. And the program overall, as CMS has reported, is delivering access to medications for most beneficiaries and saving them millions of dollars as a group.

Clearly, we should and are doing all we can to ensure that Part D is working for <u>all</u> enrollees especially those for whom the transition to Part D has been difficult. At the same time, we should recognize that a great number of people are working assiduously to continue to improve Part D's implementation. Significant progress has been made on this front with CMS, states and health plans working to close the information gaps in the system that were at the heart of the program's early implementation challenges. I want to stress again that we continue to see improvements in the system. As a sign of these improvements, over the last half of February, we continued to see decreases in both call volumes and call wait times. Voluntary enrollment is up sharply – as CMS announced last week. And this is consistent with the trends at Ovations and UnitedHealth Group.

We are encouraged by this progress. We at Ovations and UnitedHealth Group are committed to working with you, CMS, the states, pharmacists and beneficiaries to address the current challenges and fulfill the promise of what is an ambitious and valuable program. We hope that we can be a constructive force to that end and look forward to working with you in the weeks, months and years to come. We especially appreciate the Committee's leadership on this important matter and thank you for the opportunity to share our thoughts. I would be happy to answer any questions you might have for me.

MR. DEAL. Thank you, Mr. Paul. Ms. Walsh.

MS. WALSH. Chairman Deal, members of the committee, it is an honor to be here today to speak with you about Maine's experience with the implementation of the Medicare drug benefit. My name is Jude Walsh and I serve as the Director of Pharmacy Affairs in Maine and overall responsibility for the implementation of the Medicare benefit in my State. I would like to begin with some background on Maine, our experience with the implementation of the Part D benefit, and our remaining concerns.

There are approximately 45,000 dual eligible individuals enrolled in the MaineCare Program, Maine's Medicaid program. Maine, like many other States, has invested a tremendous amount of time and effort to prepare for the safe transfer of its duals to Part D. Part of this preparation included an analysis of the formularies of all the prescription drug plans available to our duals. This analysis showed that one out of every four dual members had been randomly assigned to plans where less than 60 percent of their drugs were covered and available without prior authorization. We sought and gained permission from CMS to intelligently reassign these members to plans that covered 95 percent of their drugs.

Maine's preparation included working closely with our pharmacists. They alerted us to a potential major problem in late December. They were concerned that they could not verify Part D eligibility for 40 to 50 percent of their dual clients. This meant that they would not be able to get the plan to pay for the members' prescriptions. In addition, we had received our MMA file, that is the Medicare file that we get from CMS, the file that identifies the duals, and this file showed that only four people out of the 45,000 who are on the file were eligible for low-income subsidies, when in fact, all 45,000 people should have been, had the subsidy available to them. These issues prompted our Governor to draft an urgent letter to Dr. McClellan.

We also set up a toll free hotline that low-income seniors could call for information about Part D, assisted them with enrollments into plans and helped people apply for low-income subsidies. The last week of December, we were averaging 15,000 calls a day from confused seniors. This call volume was very difficult to manage for a State of Maine's size. This hotline enabled us to quickly respond during the first few days of January, when thousands of Maine's seniors were not able to access their Federal drug benefit. State staff were monitoring phone lines over the New Year's holiday weekend. On New Year's Day we immediately began hearing about problems. We tried contacting plans and some were closed or did not answer their phones. Pharmacists were put on hold an

hour or more and at one point, our largest independent pharmacy had all 13 outgoing lines on hold with plans.

By Tuesday, January 3rd we were up to 18,000 calls from people who could not get their medications. Some members were being charged a $250 deductible and over $100 in co-pays. Many were leaving pharmacies without life sustaining medications. It was chaos, people were calling nonstop. Many people could not get their medicine. They were crying and they had nowhere else to turn. The State had to act and at 11:30 in the morning on the 3rd, the Governor had heard enough. He instructed us, and I think Maine was the first State in the country, to restore our pharmacy benefit for these people.

We created an emergency override for pharmacists to bill the State when duals were being charged excessive co-pays or were being denied transition coverage of drugs. This also allowed pharmacies to bill us when nursing homes duals were denied injectable medications like insulin and cancer medications. To date, we have filled over 115,000 prescriptions for over 50,000 people using this override. We continue to provide and need this safety net. We still have more than 12 percent of our members missing their low-income subsidy indicators. We have spent over $6 million and have asked for an extension to continue this critically needed safety net through the end of March.

We would like to acknowledge the valiant efforts of CMS staff to work with us, both over the phone and in person, to address our concerns. We have seen improvements since the benefit began. Many more people now have the correct low-income subsidy indicators on their MMA file. We have benefited from their sound advice on working with pharmacies to make sure that Part D plans are billed prior to using this override in billing the State. We appreciate the opportunity to apply for the Medicare demonstration waiver and the promise of repayment from CMS.

There are, however, issues with the Medicare Part D benefit that persist, especially for the dual eligible population. The disparities between the plans and the number of plans to choose from are confusing with dual eligibles often auto-assigned into plans where drug formularies do not match their drug needs. They have mandatory co-pays. In fact, we have heard that some pharmacies have denied filling medications for failure to pay co-pays. This Federal flaw has resulted in legislation pending in Maine that would provide additional co-pay assistance to our duals.

Their drug benefit is now divided even further with some medications covered by Medicaid in the form of excluded drugs, some covered by Medicare Part B, like cancer medications, and the remaining drugs covered by Part D, none of which is held in a single drug profile,

creating increased opportunities for the occurrence of adverse events, drug-to-drug interactions and duplicate therapy. Prior authorization criteria vary from plan to plan, fair hearing requests take a minimum of 17 days, transitional coverage is inconsistently applied depending on the plan, and enrollments average six to eight weeks and it is difficult to administer when members want to move to a new plan.

Maine is also adversely impacted by the clawback. Even with the Secretary's recent reduction in the clawback amount, we are still being charged millions of additional dollars for a benefit we had no role in designing and whose current and future cost we have no influence in controlling. The clawback is, perhaps, the most accurately named and least confusing aspect of the Medicare drug benefit. It uniformly punishes States for effectively controlling prescription drug costs, while rewarding States that have suffered annual double digit increases due to inaction.

For the next three years CMS will be using a national trend rate on prescription drug growth of over 9 percent, when in fact, Maine has been containing annual drug growth to less than 3 percent. The Federal drug benefit was not ready January 1st and it is still not ready for everyone today. We doubt that CMS would have ever allowed a State Medicaid program to implement a benefit as flawed as this one remains. We appreciate the enormity of the task before CMS, but urge Congress to act and fix the Part D benefit, including changing the base year for the calculation of the clawback and using actual State trend rates instead of National projections. I thank you for the opportunity to testify and will be available for questions.

[The prepared statement of Jude Walsh follows:]

PREPARED STATEMENT OF JUDE E. WALSH, SPECIAL ASSISTANT, GOVERNOR'S OFFICE OF HEALTH POLICY AND FINANCE, STATE OF MAINE

Chairman Deal, Representatives Brown, Dingell, Barton, and members of the Committee:

It is an honor to be here today to speak with you about Maine's experience with the implementation of the Medicare Drug Benefit. My name is Jude Walsh and I serve as the Director of Pharmacy Affairs in Maine and have overall responsibility for the implementation of the Medicare Drug Benefit in my state.

I would like to begin with some background on Maine, our experience with the implementation of the Part D benefit and our remaining concerns. There are approximately 45,000 dual eligible individuals enrolled in the MaineCare Program – Maine's Medicaid Program. Maine, like many other states, has invested a tremendous amount of time and effort to prepare for the safe transfer of its duals to Part D. Part of this preparation included an analysis of the formularies of all the Prescription Drug Plans available to our duals. The analysis showed that 1 out of every 4 dual members had been assigned to plans where less than 60% of their drugs were covered and available without prior authorization. We sought and gained permission from CMS to intelligently reassign these members to plans that covered over 95% of their drugs.

This preparation included working closely with our pharmacists. They alerted us to a potential major problem in late December. They were concerned that they could not verify Part D eligibility for 40-50% of their dual clients. This means that they would not be able to get the plan to pay for that members' prescriptions. In addition, we had received our MMA file – the file identifying duals from CMS- that had only 4 people eligible for low-income subsidies when all 45,000 duals should have had this subsidy available to them. These issues prompted the Governor to draft an urgent letter to Dr. McClellan.

We also set up a toll free hotline where low-income seniors could call for information about Part D, assisted with enrollment into plans and helped people apply for Low Income Subsidies. The last week of December we were averaging about 15,000 calls a day from confused seniors. This call volume was very difficult to manage for a state of Maine's size. This hotline enabled us to respond quickly during the first few days of January when thousands of Maine seniors were not able to access their Federal drug benefit.

State staff were monitoring phone lines over the New Year's holiday weekend. On New Year's Day we immediately began hearing about problems. We tried contacting plans and some were closed or did not answer their phones. Pharmacists were put on hold an hour or more – and at one point our largest independent pharmacy had all 13 outgoing lines on hold with plans.

By Tuesday January 3rd we were up to 18,000 calls from people who could not get their medications. In some cases they were being charged a $250 deductible and over a $100 in co pays. Many were leaving pharmacies without life sustaining medications. It was chaos. People were calling non-stop. Nobody could get their medicine. They were crying and they had no place else to turn. The State had to act. At 11:30 am Tuesday morning the Governor had heard enough. He instructed me to restore our pharmacy benefit for these people.

We created an emergency override for pharmacists to bill the State when Duals were being charged excessive co pays or being denied transition coverage. This also allowed the pharmacies to bill us when nursing home duals were denied injectable drugs like insulin and cancer medication.

To date we have filled over 115,000 prescriptions for over 50,000 people using this override. We continue to need this safety net. We still have more than 12% of our members without Low Income Subsidy indicators working. We have spent over $6 Million dollars and have asked for an extension to continue this critically needed safety net through the end of March.

There are issues with the Part D benefit that persist, especially for the dual eligible population. The number and choices of plans is confusing with duals often auto-assigned into plans with drug formularies not matching their drug needs. They have mandatory co pays – in fact we have heard that some pharmacies have denied filling medications for failure to pay co pays. This federal flaw has resulted in legislation pending in Maine that would provide additional co pay assistance. The drug benefit is divided with some medications covered by Medicaid (excluded drugs), some covered by Medicare Part B (cancer medications) and the remaining drugs covered by Part D – none of which is held in a single drug profile, creating the opportunity for drug to drug interactions and duplicate therapy to occur. Prior Authorization criteria vary from plan to plan, fair hearings requests take a minimum of 17 days, transitional coverage is inconsistently applied depending on the plan and enrollment averages 6 –8 weeks and is difficult to administer when members attempt to move to a new plan.

We would like to acknowledge the valiant efforts of CMS staff to work with us to address these concerns. We have seen improvements since the benefit began. We have taken their advice on working with pharmacies to make sure that Part D plans are billed

prior to using our override and billing the State. We appreciate the opportunity to apply for the Medicare demonstration waiver and the promise of repayment.

Maine is adversely impacted by the clawback. Even with the Secretary's recent reduction in the clawback amount we still are being charged millions of additional dollars for a benefit we had no role in designing and whose current and future costs we have no influence in controlling. The clawback is perhaps the most accurately named and least confusing aspect of Medicare Drug benefit. It uniformly punishes states for effectively controlling prescription drug costs while rewarding states that had annual double-digit increases due to inaction. For the next three years CMS will be using a national trend rate on prescription drug growth of over 9% when in fact, Maine has been containing growth to less than 3%.

The federal drug benefit was not ready January 1st and is still not ready for everyone today. CMS would never have allowed a state Medicaid Program to implement a benefit as flawed as this one remains. We appreciate the enormity of the task before CMS but urge Congress to act and fix the Part D benefit including changing the base year for calculation of the clawback an using actual trend rates instead of projections.

Thank you for the opportunity to testify. I would be happy to answer any questions you might have.

MR. DEAL. Thank you. Mr. Ettienne.

MR. ETTIENNE. Good job. Thank you. Mr. Chairman, Mr. Allen, and other members who are present today. My name is Earl Ettienne. I am a registered pharmacist and the Senior Pharmacy Supervisor for CVS Pharmacy. I am pleased to appear before you today to provide my perspectives, as well as that of CVS Pharmacy on the current status of the implementation of the Medicare Part D prescription drug benefit. CVS is, indeed, the largest pharmacy provider in the nation with over 5,500 stores in 36 States. Last year we filled in excess of 400 million prescriptions and had annual sales in excess of $37 billion. In my role as the Senior Pharmacy Supervisor I am responsible for overseeing the operations of all CVS pharmacies in the Washington metropolitan area. For example, I am responsible for assuring that all these pharmacies and the pharmacists that practice in these stores abide by the highest standards of professional practice, comply with Federal and State regulations relating to the practice of pharmacy, and are aware of important changes in prescription drug benefit programs such as Medicare Part D.

Without a doubt, the implementation of Medicare Part D created many challenges for CVS Pharmacy, the millions of beneficiaries that obtain prescriptions from our pharmacies, as well as the many thousands of pharmacists that practice in our stores. However, as a large pharmacy provider, we knew that it was very important to do all that we could to make this benefit work for the patients and for the pharmacists that we serve. Our pharmacists have spent countless hours helping seniors better understand the new Medicare Part D drug benefit. They spend time educating them about their various plan options, as well as obtaining the information necessary to accurately fill and bill their prescriptions.

Seniors rely on their pharmacists, whether they go to an independent pharmacy or to a chain pharmacy, to help them with all these tasks.

To that end, I would agree with Secretary Leavitt's characterization recently that said the pharmacists are, indeed, the heroes during the early stages of this implementation. I noted today that there were several members who also echo those same sentiments. No doubt that the beginning of the Medicare Part D program was rough primarily because pharmacies lacked important beneficiary billing information and co-pay data on many Medicare beneficiaries that had enrolled or had been assigned to a Part D plan. This is because many beneficiaries have not received the data from the plans in which they had been enrolled, nor did the pharmacies have access to this information through the E1 query eligibility system early in the program.

Unfortunately, the long initial wait times for the various plans, the help lines necessary to obtain the necessary billing information slowed down the prescription filling process for our pharmacists. These long waits also increased the amount of time that a Medicare beneficiary had to wait to get their prescription filled. We know that this was particularly a problem for the dual eligibles that were transferred from Medicaid drug coverage to Medicare Part D coverage. However, the wait times have significantly lessened and our pharmacists continue to ensure that beneficiaries are provided their necessary medications.

We hope that many of the initial system start-up problems are resolved. We do remain hopeful but concerned about the significant number of individuals that might enroll just before the May 15th open enrollment period deadline. Although, since there is a gap of time between the May 15th deadline and the June 1st enrollment effective date, we are hopeful that the health plans will have time to be sure that all the necessary information will be populated in their data fields and members will have received ID cards and benefit information. I will have more to say about this just a little later. I also know that many pharmacists found some Part D plans' transition policies to be hard to understand and difficult to implement. We are working through some of these issues with CMS and the health plans, but more work needs to be done in that area.

At this point, I can say that, based on the feedback that I am receiving from the front line, from the pharmacists, the situation with Medicare Part D is clearly better as compared to days early in the program. There still remains several systematic and day-to-day issues that pharmacists have to deal with and there may be new challenges on the horizon. For example, we still believe that Congress and HHS must somehow address the enrollment lag issue and we are very concerned about how Medicare beneficiaries will react when they find themselves

in the coverage gap or the donut hole this summer. We also believe that there could be a significant log jam at the end of March, which is the end of the special 90-day transition period.

Millions of beneficiaries will need to either seek an exception in order to continue on non-formulary drugs that they are taking, or have their non-formulary medication switched to a formulary drug. This could create significant problems for physicians, for pharmacists that are trying to assure that the beneficiaries remain on medications that are appropriate to treat their medical conditions. We are helping our pharmacists better understand the exceptions and appeals process so they can explain it to the Medicare beneficiary, if asked. Plans need to begin to address these transition issues now before the last week of the month.

Let me talk just briefly about education and training. There have been many questions in the press about whether pharmacists were adequately educated and prepared for the many aspects of the Part D implementation and whether CMS did all that it could to help pharmacists prepare. In my view, we embraced this task to educate almost 15,000 plus pharmacists and over 35,000 support personnel before October 1st about all aspects of Part D, as well as keep them informed of the many changes that have occurred since then. Fortunately, we started the process last June through multiple education modules. We built on the information learned in prior continuing education programs so that our pharmacists felt comfortable that they knew what was needed to support our Medicare Part D eligible customers.

Moreover, not all pharmacies have the same technological capabilities in their pharmacy computer systems. This may have made it easier for some pharmacies than others to use some of the new technology tools that have been put in place to facilitate the implementation of this benefit. Let me just briefly describe for you some of the many activities that CVS Pharmacy designed to help the pharmacists understand Part D and stay updated on the many changes that have taken place since the start of the program.

We have sponsored multiple continuing education events for our pharmacists on Part D. These included special online, as well as live training sessions that began last June. Every pharmacist had to complete three training sessions online and we carefully tracked each session. We developed an internal intranet website that is updated regularly with new information about the Part D benefit as it becomes available. We have weekly calls to review new updates relating to the Part D benefit in general, as well as specific issues that pharmacists need to know about certain Part D plans.

New information is coming out every day, from CMS, the States, and from the plans. It is important for our pharmacists to keep up to date but frankly, it can be challenging to do so. In my view, pharmacists understand their important obligation to their patients and are doing the best they can to keep up with this information overload. CVS also understands its important corporate role in helping our pharmacists serve Medicare beneficiaries by offering them a structured way to keep on top of these changes.

There will be some challenges moving forward. We expect challenges with the enrollment logs, formulary issues, as well as billing issues. In the interest of time, my written testimony will cover these in great detail. In conclusion, we have obviously come a long way since January 1st, but we have opportunities to make improvements. CVS Pharmacy is committed to doing all it can to making this benefit work through education of our pharmacists, outreach to seniors, and participation in various government and private sector initiatives to create efficiencies in the delivery of this benefit. We appreciate the opportunity to provide our views to the subcommittee and we stand ready and willing to help people live longer, healthier, happier lives.

Thank you.

[The prepared statement of Earl Ettienne follows:]

PREPARED STATEMENT OF EARL ETTIENNE, SENIOR RX SUPERVISOR, CVS PHARMACY

Mr. Chairman and Members of the Subcommittee on Health: I am Earl Ettienne, a registered pharmacist and Senior Pharmacy Supervisor for CVS Pharmacy. I am pleased to appear before you today to provide my perspectives and that of CVS Pharmacy on the current status of the implementation of the Medicare Part D prescription drug benefit program.

CVS Pharmacy is the largest pharmacy provider in the nation with over 5,500 stores in 36 states. Last year, we filled over 400 million prescriptions and had annual sales of $37 billion. In my role as Senior Pharmacy Supervisor, I am responsible for overseeing the operations of all CVS pharmacies in the Washington, D.C. metropolitan area. For example, I am responsible for assuring that all these pharmacies – and the pharmacists that practice in these stores – abide by the highest standards of professional practice, comply with Federal and state regulations relating to the practice of pharmacy, and are aware of important changes in prescription drug benefit programs, such as Medicare Part D.

Medicare Part D: Past and Present

Without a doubt, implementation of Part D created many challenges for CVS Pharmacy, the millions of beneficiaries that obtain prescriptions from our pharmacies, as well as the many thousands of pharmacists that practice in our stores. However, as a large pharmacy provider, we knew that it was important to do all we could to make the benefit work for the patients our pharmacists serve.

Our pharmacists have spent countless hours helping seniors better understand the new Medicare Part D drug benefit, educate them about their various plan options, and obtain the information necessary to accurately fill and bill their prescriptions. Seniors rely

on their pharmacist – whether they go to an independent or chain pharmacy – to help them with all these tasks. To that end, I would agree with Secretary Leavitt's recent characterization of pharmacists as being the "heroes" of the early stages of the implementation of this benefit.

No doubt that the beginning of Medicare Part D was rough primarily because pharmacies lacked important beneficiary billing information and copay data on many Medicare beneficiaries that had enrolled or been assigned to a Part D plan. That is because many beneficiaries had not received these data from the plans in which they had been enrolled, nor did pharmacies have access to this information through the "E1 query" eligibility system early on in the program.

Unfortunately, the long initial "wait times" for the various plans' "help lines" to obtain the necessary billing information slowed down the prescription filling process for the pharmacist. These long waits also increased the amount of time that a Medicare beneficiary had to wait to get their prescription filled. We know that this was particularly a problem for the dual eligibles that were transferred from Medicaid drug coverage to Medicare Part D coverage. However, the wait times have since significantly lessened and our pharmacists are continuing to ensure that beneficiaries are provided their necessary medications.

We hope that many of the initial system start up problems are resolved. We do remain hopeful but concerned about the significant number of individuals that might enroll just before the May 15th "open enrollment period" deadline. Although, since there is a gap of time between the May 15th deadline and June 1st enrollment effective date, we are hopeful that the health plans will have time to be sure that all the necessary information will be populated in their data fields and members will have received their ID cards and benefit information. I will have more to say about that a little later. I also know that many pharmacists found some Part D plans' transition policies to be hard to understand and difficult to implement. We are working through some of those issues with CMS and the health plans, but more work needs to be done in that area.

At this point, I can say that based on the feedback that I am receiving from pharmacists on the front line in our pharmacies, the situation with Medicare Part D is clearly better as compared to the early days of the program. There still remain several systemic and day-to-day issues that pharmacists have to deal with, and there may be new challenges on the horizon.

For example, we still believe that Congress and HHS must somehow address the "enrollment lag" issue, and we are very concerned about how Medicare beneficiaries will react when they find themselves in the "coverage gap" or "donut hole" this summer. We also believe that there could be a significant "logjam" at the end of March, which is the end of the special 90-day transition period. Millions of beneficiaries will need to either seek an exception in order to continue on the non-formulary drug that they are taking, or have their non-formulary medication switched to a formulary drug. This could create significant problems for physicians and pharmacists that are trying to assure that beneficiaries remain on medications that are appropriate to treat their medical conditions.

We are helping our pharmacists better understand the exceptions and appeals process so that they can explain it to a Medicare beneficiary if asked. Plans need to begin to address these transition issues now before the last week of this month.

Education and Training of Pharmacists

There have been many questions in the press about whether pharmacists were adequately educated and prepared for the many aspects of Part D implementation, and whether the Centers for Medicare and Medicaid Services (CMS) did all it could to help pharmacists prepare. In my view, we embraced this task to educate almost 15,000 plus CVS pharmacists and over 35,000 pharmacy support personnel before October 1st about

all aspects of Part D, as well as keep them informed of the many changes that have occurred since then.

Fortunately, we started this process last June and through multiple educational modules. We built on the information learned in prior continuing education programs so that our pharmacists felt comfortable that they knew what was needed to support our Medicare Part D eligible customers. Moreover, not all pharmacies have the same technological capabilities in their pharmacy computer systems. This may have made it easier for some pharmacies than others to use some of the new technology tools that have been put in place to facilitate the implementation of the benefit.

Let me describe for you some of the many activities that CVS Pharmacy designed to help our pharmacists understand Part D, and stay updated on the many changes that have taken place since the start of the program:

- CVS sponsored multiple continuing education events for our pharmacists on Medicare Part D. These included special online and live training sessions that began last June. Every pharmacist had to complete three training sessions online, which was carefully checked and tracked;
- We developed an internal intranet website that is updated regularly with new information about the Part D benefit as it becomes available;
- We have weekly calls to review new updates relating to the Part D benefit in general, as well as specific issues that pharmacists need to know about certain Part D plans.

New information is coming out every day both from CMS, states, and the plans. It is important for our pharmacists to keep up to date, but frankly it can be challenging to do so. In my view, pharmacists understand their important obligations to their patients and are doing the best they can to keep on top of this "information overload." CVS also understands its' important corporate role in helping our pharmacists serve Medicare beneficiaries by offering them a structured way to keep on top of these changes.

Challenges Moving Forward with Part D

Let me touch briefly on some of the challenges that remain with Medicare Part D implementation. I have already alluded to some of these in my previous remarks, but will expand on them here:

- ***Enrollment Lag:*** Congress and the Administration should address this "enrollment lag" issue by setting benchmarks that are easily understood. The key is to insure that the enrollment information and subsidy approval process must be completed and the results populated into the pharmacy databases.

  Additionally, the patient needs to have received their ID card and benefit information. With that as the guiding principle, you may want to consider a 30-day enrollment processing window. However, if plans can complete the process faster than that, then eligibility would become effective sooner. We suggest that CMS publish the time it takes on average for health plans to complete the process above, and let customers use that as a factor in choosing between health plans. By doing that, I think you will see the marketplace adopt more improved processes. But more importantly, the customer will experience a positive service encounter.

- ***Formulary Issues:*** As you know, each Part D plan has a different drug formulary, with different cost sharing tiers as well as different drugs covered under each tier. Many plans are also using cost and utilization management tools such as prior authorization and step therapy for these formulary drugs. Plans can also change formulary drugs with 60 days written notice. Some drugs are

covered both under Medicare Part B and Medicare Part D, depending on how they are administered or used. Each plan has a different transition policy.

Keeping current on all this information, as well as staying up to date on any changes, can be challenging for physicians, pharmacists, and the beneficiaries. While pharmacies have adapted to dealing with the administrative burdens of third party prescription plans, we think that these issues will significantly multiply under Part D programs. Administration of these Part D formularies at the pharmacy counter will increase costs for pharmacists and slow down the filling of prescriptions.

We are trying to resolve some of these issues by working with the health plans to develop "standard electronic real time messages" that will be sent back to the pharmacists from the plans. These messages will give more information to the pharmacist that will help reduce the amount of time that pharmacists may have to spend in resolving these formulary-related issues.

It would also help tremendously if plans would work directly with beneficiaries that need to be moved from a non formulary drug to a formulary drug before that beneficiary returns to the pharmacy counter. This will allow the pharmacist to spend more time talking to their patients about appropriate use of their drug therapy, rather than resolving third party administrative problems.

Billing Issues: If the pharmacist does not have accurate billing information, the pharmacist cannot bill the appropriate Part D plan or charge the appropriate copay. This situation occurred many times during the early days of the program, and still presents a problem for the pharmacist as a result of beneficiaries who are "late enrollers" or "late switchers." Accurate and up to date billing data are the life blood of the pharmacy billing systems. However, if we can address the "enrollment lag" issues I mentioned earlier, this could eliminate many of our "billing" concerns. If not corrected, we will continue to have issues with "late enrollers" and "late switchers."

Moreover, we face continued economic risk from prescriptions that have been billed in good faith to the Wellpoint POS system. This system was put in place to be a "back stop" plan for dual eligibles who had not been auto assigned to a Part D plan. There was some confusion during the early stages of the program due to a lack of good billing information for the dual eligibles. We are now being told that many of these POS claims may have to be reversed and then rebilled by the pharmacy to another Part D plan or to the Medicaid program. This just adds another level of complexity, increases our cost to fill Medicare Part D prescriptions, and potentially puts pharmacies at more economic risk.

Conclusion

We have obviously come a long way Since January 1st, but we have opportunities to make improvements. CVS Pharmacy is committed to doing all it can to making this benefit work through education of our pharmacists, outreach to seniors, and participation in various government and private-sector initiatives to create efficiencies in delivery of the benefit. We appreciate the opportunity to provide our views to the Subcommittee. Thank you.

MR. DEAL. Thank you. Mr. Lipshutz.

MR. LIPSHULTZ. Good evening, Mr. Chairman, committee members. Thank you for giving me the opportunity to testify today. My name is David Lipshutz and I am a Staff Attorney at California Health Advocates, which is an independent, nonprofit agency that is dedicated to education and advocacy on behalf of Medicare beneficiaries. We do this in part by providing technical assistance and training to the network of local State Health Insurance Programs, or SHIPs, in California known as HICAP, Health Insurance Counseling and Advocacy Program. Our experience with the implementation of Medicare Part D is based on large part with our close work with the HICAPs and other consumer assistance programs who are on the front line assisting Medicare beneficiaries.

While there are clearly Part D success stories among those that previously did not have coverage, especially if they qualify for the low-income subsidy, my focus will be on some of the ongoing problems many beneficiaries are facing, including problems that won't go away without serious changes to the programs. The most severe problems during the implementation of Part D have been felt by those who are dually eligible for Medicare and Medicaid, all of whom were switched to a new type of coverage in one day. Many have gone without their prescription drugs or have had to pay out of pocket.

Without States intervening to provide temporary emergency coverage, the crisis would be much worse. In California we have approximately one million dual eligibles. As of about last Thursday, the State of California had paid for over 300,000 prescription drugs for over 170,000 individuals. From what we have seen so far in California and we believe elsewhere, dual eligibles are worse off under Medicare Part D due to several reasons. In part, due to the breadth of the coverage, protections, and appeals, and new out-of-pocket costs that are simply out of their reach.

Linda, a client of the Health Consumer Alliance Program in San Diego, is a typical example. She is a dual eligible earning $842 a month. She takes about 30 medications. She says she cannot afford the co-pays and will be out of money for food by the end of the month. Many ongoing problems faced by dual eligibles, as I will briefly outline, impact all Medicare beneficiaries.

The first challenge for any beneficiary is trying to understand and use the complex new Part D benefit. The analysis of whether or not to enroll in a particular plan does not end at whether a drug is covered; a beneficiary must find out at what cost. The tier placement of a drug can mean the difference in paying a set co-pay of a few dollars per month or a large percentage for a very costly drug. Utilization management tools that are applied to covered drugs, such as prior authorization, may bring down plan costs, but they also serve as a barrier to getting drugs.

At best, information regarding utilization management is difficult to obtain from the plans. We have seen utilization management used in very restrictive ways, effectively denying medications for enrollees, including medications that people have already been stabilized on. I would like to put forth the example of Mr. H., a 23 year old Medicare beneficiary in El Dorado County who was stabilized on an anti-psychotic drug prior to joining the Part D plan in January. Although his new plan covered his drug, as it is amongst one of the required categories, the plan did not allow for the amount and quantity prescribed by his treating psychiatrist. Mr. H's family contacted his plan in early January and his psychiatrist wrote two separate requests to the plan to cover his drug in the requested dosage amount. The local HICAP program later intervened toward the end of the month, a plan representative explained that the plan had not responded because the physician had not used the correct form. Mr. H. changed plans in February.

Information about transition plans, which are meant to give a first fill of non-formulary drugs to new enrollees, has also been difficult to obtain and to access. Enrollees who are able to get their transition supply are not getting the notices they need to take directions and to take the next affirmative steps. This will be an ongoing issue as people either become newly eligible for Part D or change plans and find that their plans do not cover the drugs that they need. California is a culturally rich and diverse State. Non-English speaking beneficiaries are not being well served by Part D plans in California. One of our staff members in Sacramento who helped over 300 Spanish speaking Medicare beneficiaries in the last few months listened as her clients explained that their plans either have no or limited bilingual staff or had a Spanish language voice mail where messages were left but unreturned for weeks. Problems, of course, are worse for people who speak languages other than Spanish.

Some rural counties in northern California have only one local pharmacy that contracts with only one Part D plan, one that is about the benchmark for dual eligibles and others with the low-income subsidy. Plans have a wide discretion in how they design their exceptions process including the form of request and the level and type of medical evidence a supporting physician must provide. Many doctors whose participation is critical for beneficiaries report that they do not want to participate in this process because it is too burdensome for them.

In addition to these ongoing issues, we are not out of the woods yet. There is a pending crisis once State emergency drug coverage runs out for dual eligibles and when those who have been able to access transition first fills find that their drugs are not covered. This will be felt most, perhaps, by Part D enrollees who will be locked into their plans. Medicare beneficiaries deserve a prescription drug benefit they can

understand and easily access. While some individuals are successfully getting their prescriptions filled, many problems encountered by Part D enrollees will not go away without further attention and intervention. Thank you for the opportunity to provide these comments.

[The prepared statement of David Lipshutz follows:]

PREPARED STATEMENT OF DAVID A. LIPSHUTZ, STAFF ATTORNEY, CALIFORNIA HEALTH ADVOCATES

I. INTRODUCTION

California Health Advocates (CHA) is an independent, non-profit organization dedicated to education and advocacy efforts on behalf of Medicare beneficiaries in California. Separate and apart from the State Health Insurance Program (SHIP), we do this in part by providing support, including technical assistance and training, to the network of California's Health Insurance Counseling and Advocacy Programs (HICAPs) with which the SHIP contracts to assist California's Medicare beneficiaries and their families. CHA also provides statewide technical training and support to social and legal services agencies and other professionals helping Californians with questions about Medicare. Our experience with the implementation of Medicare Part D is based in large part on our close work with the HICAPs and other consumer assistance programs that are on the front line assisting Medicare beneficiaries.

It is clear that the new Part D prescription drug benefit can provide needed prescription drug coverage for those who previously had none, and individuals eligible for the low-income subsidy (LIS) will receive the new benefit at very little cost. But the first two months of the program demonstrates many of the structural defects in the design of the new program that relies solely on commercial companies to provide the new benefit in widely varying ways. By Secretary Leavitt's own admission, the roll-out of Medicare Part D has been a "difficult transition" and, although the Centers for Medicare and Medicaid Services (CMS) has worked hard to make some incremental improvements, many problems with Part D will not go away due to flaws in the basic design of the benefit and its operation. In this written testimony, we first describe the problems Part D enrollees now face –and will continue to face – as the Part D program progresses. Secondly, we use our experience with current implementation problems to analyze broader structural flaws with Part D and propose some recommendations to make the benefit work better for all beneficiaries.

II. IMPLEMENTATION OF MEDICARE PART D -- ONGOING PROBLEMS FOR BENEFICIARIES

As widely reported by Medicare beneficiaries, advocates, pharmacies, physicians and the media, there have been myriad problems with the implementation of Part D. While many individuals are getting their prescription drugs, and some improvements have been made to correct problems in regard to data issues and Part D plan phone accessibility, beneficiaries still face numerous problems that will not get better without fundamental changes made to the way the program is designed and administered. Without addressing the issues outlined below, Medicare beneficiaries will continue to face problems navigating Part D and getting the medications they need at the lowest cost.

Overview

The HICAP network and other advocates around the country report that their clients are overwhelmed by the sheer number of choices and complexity of Part D plans. Some were auto assigned to a plan without regard to their pharmaceutical needs while others were faced with the complexity of choosing a plan from dozens of different designs. Once in a plan many have been unable to obtain their prescription drugs or have had to

pay full retail prices when their subsidy status was inaccurately recorded by CMS or the plan. Advocates report that those who are dually eligible encounter the most dire problems, but many of these problems can and do affect Medicare beneficiaries regardless of their economic status.

Over 6 million dual eligibles had their drug coverage switched on a single day from Medicaid to Medicare, resulting in massive systems failures at the pharmacy level, the plan level, at 1-800-MEDICARE and the Medicare website. The sheer volume of dual eligibles, combined with their generally poorer health status and inability to pay for their own medications, swamped the resources of most local programs designed to help Medicare beneficiaries navigate this new benefit. Many Part D enrollees simply did not get their prescription drugs, and continue to experience difficulty due to a number of problems, including:

- CMS and contractors' databases fail to reflect correct eligibility status.
- Consumers, advocates, and pharmacists are unable to get through to Part D plans.
- When reached, 1-800-MEDICARE and Part D plan customer service representatives are often unable to provide accurate information.
- Dual eligibles were auto-assigned to Part D plans without regard to their pharmaceutical needs or their ability to pay premiums for Medicare Part A and B benefits in MA-PD plans.
- CMS' "backup" point of service system (Anthem/Wellpoint) fails to provide prescription drugs to dually eligible beneficiaries.
- Widespread system failures result in pharmacies charging the wrong cost-sharing for drugs, causing duals to go without critical medications when they are unable to pay.
- Part D plans and contracting pharmacies fail to honor transition plan "first fill" obligations, and
- Consumers of all economic circumstances are unable to file exceptions and appeals with Part D plans to get the drugs they need.

Understanding the Benefit

California HICAP counselors and their counterparts nationwide have been working tirelessly to help educate Medicare beneficiaries about the new Part D benefit and assist them in exploring their enrollment options. In addition to the unprecedented volume of demand for their services, the nature and structure of the Part D benefit injects a level of complexity that requires significantly more time, effort and expertise in counseling each consumer. Program managers estimate that most people choosing a plan require several hours of counseling time and often multiple counseling sessions (each of several hours in length) to collect information about their drug usage and research plans that cover those drugs at an affordable copayment and at the pharmacy of their choice.

The sheer number of drug plans available presents an overwhelming choice for most beneficiaries. Each plan differs in structure, benefits, and costs and some are sold by multiple entities under co-branding agreements with the plan sponsor. One Part D sponsor's product in California, for example, is being sold (or "co-branded") by 14 different insurance companies; another sponsor co-brands with 12 different companies. In California, 18 sponsors offer 47 stand-alone prescription drug plans (PDPs). In addition, beneficiaries can also choose from varying numbers of Medicare Advantage plans, both with and without prescription drug benefits. In Los Angeles, for example, there are approximately 70 different PDPs and MA plans from which to choose. Tiered formularies, utilization management tools (such as prior authorization) and price differences between contracting pharmacy networks further complicate the decision-making process. In addition, this information is not always available and accurate on the Medicare website.

Medicare beneficiaries are unable to differentiate between PDPs and the various MA plans such as HMOs, PPOs, Private Fee for Service Plans, and Special Needs Plans. Some MA plans include prescription drugs (MA-PDs) in their package of Medicare Part A and B services and others don't. Consumers are understandably baffled by the complexity and number of choices and can't be expected to understand the myriad of details necessary to choose the most appropriate plan for their needs.

Enrollment and Eligibility Issues

Unlike enrollment into Medicare Parts A and B, which is handled by the Social Security Administration, individuals must choose a Part D plan from a vast array of choices and purchase a particular Part D plan in order to get the new prescription drug benefit. Computer exchanges of data between Part D plans, the Centers for Medicare and Medicaid Services (CMS) and its contractors complicate beneficiary enrollment and disenrollment and lead to gaps in coverage. Multiple levels of communication and data exchanges must occur before medications can be dispensed by a pharmacy contracted with a Part D plan.

The pharmacist must electronically query the plan to determine whether a beneficiary is enrolled in that plan, whether the drug is on the plan's formulary, whether a deductible applies, and what copayment responsibility exists for the particular drug covered by the plan. If that data is not readily available the pharmacist must phone the plan to obtain this information. The plan cannot confirm the beneficiary's enrollment and copayment responsibility with the pharmacy until CMS has confirmed the beneficiary enrollment and subsidy status, and whether the person is enrolled in another plan or covered by an employer plan receiving the federal subsidy for employers. Any data flaw along this chain will result in medications being withheld or beneficiaries paying the wrong price, if they can afford it, for their medications.

Data flaws affect all Medicare beneficiaries regardless of their status, but they affect those who are dually eligible for Medicare and Medi-Cal (Medicaid) most acutely. While both consumer advocates and California's state Medicaid Agency (Department of Health Services - DHS) report incremental improvements in CMS data systems reflecting eligibility and enrollment, there are continuing data problems that lead to gaps in coverage for dual eligibles. The current "back-up system" for dual eligibles who are not assigned to a plan – the Point of Sale system run by Anthem/Wellpoint – allows many duals to fall through the cracks. Instead, they must rely on the state's temporary emergency funding in order to obtain their prescription drugs. Unless California takes further action, however, this emergency funding will run out in a matter of weeks, possibly months. More than half of all states have had to assume responsibility for the poorest of their residents to make up for the failures of the national program.

According to the state Department of Health Services, an estimated 10,000 Californians will become dually eligible for Medicare and Medi-Cal each month, thus becoming a dual for the purposes of Part D benefits only. DHS anticipates that despite current efforts to alleviate data problems, there will be ongoing delays in CMS auto-enrollment of these individuals into a Part D plan. Other states will have the same, chronic problem transitioning dual eligibles from their state Medicaid program to Medicare for their prescription drug coverage.

In addition, there will continue to be delays in eligibility information when dual eligibles – or any other Part D enrollee during a permissible enrollment period – first enroll in a plan or exercise their right to change plans. Enrolling in or changing drug plans requires complex data exchanges between the old plan, CMS, the new plan, and the plan's contractors and sub-contractors. This information can take many days or several weeks to be accurately displayed in the system. Changes made toward the end of the month often will not show up in the system until later the following month, making it

difficult to obtain drugs in the early part of the month after enrolling in or switching plans.

In late 2005, HICAPs and other Medicare counselors helped numerous dual eligibles analyze their auto-assigned plans and find other plans that better suited their individual needs. These duals who "did their homework" however, were penalized in January when they found that their records were in chaos; the Anthem/Wellpoint POS system failed and did not help them.

Example: Helen, age 86, a dual eligible of Humboldt County, changed her auto-assigned plan on December 15th to one that better suited her drug needs. In January, her new plan had no record of her enrollment in the plan or her status as a dual eligible. She went 3 weeks without her medications because she could not afford to pay for them, until she was able to obtain emergency coverage through the state. She did not receive her new plan's enrollment card until February 10th.

Example: Dorothy, a Medicare beneficiary from the central coast of California, chose an AARP Part D plan in early November 2005, but days later informed them that she no longer wanted this coverage. Despite confirmation of her request from AARP at the time, Dorothy has had the AARP Part D premiums deducted from her Social Security check for both January and February and it is not clear when that deduction will end or when those premiums will be refunded.

Low Income Subsidy (LIS)

In addition to problems with eligibility and enrollment data, many HICAPs and other consumer assistance programs report that there are still widespread problems with data available to pharmacies and plans that accurately reflect individuals' LIS eligibility status and the correct amount of their prescription drug copayment. This problem is most acute when an enrollee switches plans or enrolls in a Part D plan for the first time, leading to LIS enrollees being charged inappropriate copayment amounts. This problem occurs for all LIS enrollees – not just dual eligibles.

Example: Mildred, age 86, a dual eligible resident of Del Norte County, changed her auto-assigned plan in December 2005 to one that better met her drug needs. Her eligibility information for the LIS, however, did not follow, and she had to pay approximately 15% of her income on drugs. After 10 phone calls to various entities by the local HICAP, she found that she must wait 6-8 weeks for reimbursement from her plan.

Transition Processes

Despite CMS' request to Part D plans that they extend their transition "first fill" coverage of non-formulary drugs through March, HICAPs report that many Medicare beneficiaries are unable to access such coverage due to lack of information about transition policies at Part D contracting pharmacies and/or the unwillingness of pharmacies to provide such supplies.

Information about these transition processes have been extremely difficult to obtain through the plans; this issue is a recurring one and people will continually become newly eligible for Part D and will find that their new plan does not cover the drugs they are currently taking. The transition process is meant to allow an enrollee to request an exception so that his/her non-formulary drug can be covered or to change drugs or drug plans. Many beneficiaries who have been given a transitional supply of non-formulary drugs, however, are not receiving notices from plans and contracting pharmacies

informing them what they should do next (e.g., talk with their doctors about alternate drugs, file an exception request, or change plans).

Language Access

CMS standards require Part D call centers to accommodate non-English speaking beneficiaries. Based upon reports from HICAPs and other advocates, however, non-English speakers in California, a culturally and linguistically diverse state, are not being accommodated.

In our agency's Sacramento office, we answer phone calls from Medicare beneficiaries that for whatever reason are not appropriately routed to their local HICAP program. One of our staff members, Marta Erismann – also a HICAP counselor – has personally assisted over 300 Spanish speakers in the last few months, many of whom have been unable to communicate with their plans.

Many of Marta's Spanish-speaking clients reported that their Part D plans did not have bilingual representatives, or if they did the number of bilingual staff was limited and unable to respond to the demand. Many told her that they were put on hold for many hours waiting for the Spanish-speaking counselor, only to be disconnected after waiting for an hour or more. Many were told numerous times to "call back in one hour" on several continuous days. Numerous callers reported only being able to leave a voice-mail message with their plans, many leaving messages that went unreturned for two or more weeks. On the occasions when non-English speakers were able to talk to plan staff, the staff was not generally knowledgeable about Part D and unable to respond to their questions.

The problems for non-English speakers carry over into pharmacies, as well. Many pharmacists, due to lack of bilingual staff, are not able to communicate to Medicare beneficiaries the reason they are being denied medications. Many of these individuals leave their pharmacies, not understanding why they can not get their medications.

Rural Issues

In several rural counties of Northern California, the local pharmacy is contracted with a single PDP, one with a premium too high for duals and people with low income assistance. Other than a Regional PPO plan, there are no MA-PD plans in these counties. People in all but one PDP must drive many miles to the nearest chain pharmacy over mountain roads that become impassable in bad weather. The nearest chain pharmacies do not provide home delivery services that are provided by the local pharmacy, a serious problem for people who cannot get to the contracted pharmacy. Mail-order prescriptions offered by other Part D plans do not always cover all needed medications, or deliver drugs in a timely fashion.

Marketing Misconduct

Amid the confusion over the new Part D benefit, HICAPs and other Medicare counselors report inappropriate marketing performed by plan representatives. Some HICAP managers describe speaking with clients who leave marketing presentations with no idea what they just had signed up for. Part D plan agents, with little or no oversight, can take advantage of the general confusion surrounding Part D and steer people towards plans that will result in enrichment of the agent, but might not be the best plan for the enrollee.

Example: The HICAP program in Ventura County reports that a Part D plan agent has apparently switched a group of board and care residents from the plans they enrolled in with HICAP's help, to the plan that the agent was selling, without regard to their individual drug or pharmacy access needs.

Added Cost Burdens for Dual Eligibles

Consumer assistance programs across the country report that many dually eligible individuals have been charged inappropriate cost-sharing for their drugs, including deductibles and copayments. Even when the low-income subsidy (LIS) is correctly applied, however, it must be made clear that most dual eligibles cannot afford the new cost burdens that are permissible under the LIS.

California is one of many states that does not force Medicaid recipients to pay prescription drug cost-sharing. While dual eligibles are automatically enrolled in the low-income subsidy (LIS, or "extra help") which covers some of their Part D expenses, dual eligibles in California (and many other states) now face additional cost burdens that are out of their reach. HICAPs and other consumer assistance programs in California are already hearing reports of people unable to pay their rent, grocery and other survival costs due to these increased cost-sharing amounts.

Unlike current Medicaid rules, pharmacies can deny drugs to those who cannot afford to pay the new cost-sharing requirements. The only place where dual eligibles will be exempt from these new obligations is in certain long term care facilities such as nursing homes, but not assisted living/residential care facilities for the elderly. This, unfortunately, creates a perverse incentive towards institutionalization (and goes against the spirit of the *Olmstead* decision).

HICAPs report that most pharmacies are not using their discretion to waive copays for LIS individuals. HICAP programs and other non-profit agencies are receiving many calls from people seeking assistance in paying the copays – for which there is currently none.

Example: A paraplegic client of the Health Consumer Alliance in California only makes $800 a month. Due to his many complicating medical issues, he is on 35 medications. He cannot afford the $3-5 co-payments for his meds. His delivery man has paid his co-pays the last two months. He says that he will have to choose between paying for his rent, food, and medications.

Example: Linda, a client of the Health Consumer Alliance in San Diego, has an income of $842 a month. She takes about 30 medications and cannot afford the $1, $3, $5 co-payments. She says that she will be out of money for food by the end of the month. If she were to move into a nursing home, she would have no copayments.

Example: Every HICAP counselor in Humboldt County, CA, reports hearing at least one client report that they will die because of their inability to afford their drug copays.

Example: One HICAP manager in the Central Valley, responding to a distraught client who could not afford her copays for her insulin, went down to the client's pharmacy to pay her copays for the month.

There are additional unintended consequences and costs faced by low-income individuals due to the problems with Part D implementation. HICAP counselors report that many of their low-income and/or non-English speaking clients do not have land-based telephone lines; instead, they rely on cell phones, sometimes using prepaid minutes. Many saw their minutes drained as they waited "on hold" for hours for a 1-800-MEDICARE customer service representative or a Part D plan representative. Some had their phone service cut off; some had to borrow funds to obtain additional minutes to continue their efforts to contact Medicare or seek information from their plans.

Exceptions and Appeals

Once transition fills and various states' emergency drug coverage run out, many more Part D enrollees will be forced to use the exceptions and appeals process in order to obtain non-formulary drugs. Current Medicare rules give Part D plans broad flexibility in how they administer their exceptions processes, including the form of request (oral or written) and the type and amount of evidence prescribing physicians must submit to prove medical necessity. Although CMS has posted a model form to be used to request a coverage determination, each plan can create its own process. Some plans are requiring the submission of clinical notes verifying that all drugs on the formulary are either less effective or harmful for the beneficiary or both. Because each plan's process is different, physicians must deal with multiple processes to adequately serve all their patients. Many doctors are unwilling to go through this process because they say the plans require too much information. Some HICAPs report that some local medical groups are establishing policies requiring scheduled office visits with physicians in order to assist with patient exceptions, in order to receive some type of compensation for their time.

Overall, Part D enrollees and those that are assisting them are having difficulty navigating the exceptions/appeals process. We fear that the volume of exceptions (along with the need to assist with these requests) will increase exponentially once current transition first fills run out (if available/accessible) and California's emergency drug coverage for dual eligibles expires.

> Example: Mr. H., a 23 year old Medicare beneficiary in El Dorado county, was stabilized on an anti-psychotic drug prior to joining a Part D plan in January. Although his new plan covered his drug, it did not allow for the amount and quantity prescribed by his treating psychiatrist. Mr. H's family began contacting his plan in early January and his psychiatrist wrote two separate requests to the plan to cover his drug in the requested dosage amount. When the HICAP program later intervened towards the end of the month because neither Mr. H. nor his psychiatrist had received a written response from the plan, a plan representative replied that the plan had not responded because the physician had not used the correct form. Mr. H. changed plans in February.

III. STRUCTURAL PROBLEMS -- PART D BENEFIT DESIGN

As referenced above, HICAP counselors and their counterparts nationwide have been working tirelessly to help educate Medicare beneficiaries about the new Part D benefit and assisting them in exploring their enrollment options. The nature and structure of the Part D benefit, however, injects a level of complexity that requires significantly more time, effort and expertise in counseling each consumer. Trying to both decipher and navigate the range of Part D plans, drugs covered on their formularies, applicable cost-sharing based upon which tier a drug is in, assessing any utilization management tools that might apply to a covered drug, and investigating which pharmacies contract with a given plan are all challenging, at best.

For further analysis of issues relating to enrollment/disenrollment protections and choices, as well as access to plan information about utilization management tools and transition plans, see our website for issue briefs we have co-authored with the Medicare Rights Center (www.cahealthadvocates.org).

Lack of Standardization

The sheer number of drug plans available that differ in structure, benefits and cost, make informed choice on the part of beneficiaries difficult to achieve. Tiered formularies, utilization management tools (such as prior authorization) and contracting pharmacy networks further complicate decision-making. In addition, the flexibility Part D plans are given in designing their exceptions process, including determining the form

of request along with the level and type of medical evidence required, hinders beneficiaries and their prescribing physicians in obtaining needed drugs.

Part D plans are required to cover all medically necessary drugs within the scope of drugs that are coverable under the Medicare statute. Many Medicare beneficiaries with chronic conditions and who take multiple prescriptions, however, are having difficulty finding plans that cover all of their prescription drug needs. Even if a particular drug is covered, plans can put higher-cost drugs in higher cost-sharing tiers, limiting the benefit of having a particular drug "covered" by a plan. Further, plans do not adequately explain the restrictions they impose on certain drugs, leaving potential enrollees uncertain whether or not the drugs would be covered for them. In other words, even if a drug is covered by a plan, it can be both unaffordable – due to its tier placement, or unavailable – due to onerous prior authorization requirements.

The Medicare program should provide a limited number of standard, uniform benefit packages, and standardize the benefit, cost sharing, and procedures provided through private plans. CMS should consult with the NAIC, industry representatives, and consumer groups to standardize the Medicare Part D benefit in the same way Medicare Supplement insurance (Medigap) products were standardized in 1990. In addition, exceptions processes should be uniform and standardized among all plans, with a single form made available to all physicians and pharmacists.

Lack of Safety Net Coverage for Dual Eligibles

When drug coverage for dual eligibles was switched from Medicaid to Medicare on January 1, 2006, dual eligibles lost much more than drug coverage administered through their state program, they lost more comprehensive coverage, with less restrictions, less cost-sharing and more due process protections. As discussed above, data exchange issues will continue to leave them with gaps in coverage and protection from high costs.

The best way to protect dual eligibles who are unable to access their drugs due to data system problems reflecting eligibility, enrollment and LIS cost-sharing, is to continue Medicaid coverage (and federal matching funds) to serve as a true payer of last resort. Absent a Medicaid extension, we recommend that the Anthem/Wellpoint system be redesigned and expanded to serve as a payer of last resort as a means of addressing all eligibility and enrollment problems that dual eligibles face (as has been recommended by California's DHS).

Expand Enrollment into Low Income Subsidy (LIS)

Many Medicare beneficiaries who are eligible for the low income subsidy have failed to apply. While as many as 8 million beneficiaries are estimated to be eligible, only 1.4 million have actually applied and been found eligible. Of those that applied, over 60% were denied not because they did not meet the income test, but because their resources were too high.

Elimination of the asset test for the LIS would greatly expand eligibility to a benefit that can truly help needy individuals with Part D costs.

Minimal Oversight and Regulation

A great deal of flexibility is given to Part D plans throughout virtually all aspects of Part D. Even during the early roll-out of Part D, when it was becoming clear that there were major problems with beneficiaries accessing their drugs due Part D plan failures in honoring transition policies and providing adequate lines of communication with beneficiaries and pharmacists, CMS continued to "request" and "recommend" that the plans extend their transition periods and provide more accessibility rather than demand it.

The Medicare program should impose more strict requirements on Part D plans, including the following:

- Stricter formulary requirements (require the plans to cover more drugs)

- Stricter transition policies (requirements, rather than recommendations, for longer "first fill" periods)
- Standardized forms and procedures for exceptions and appeals
- Accessibility standards
  - availability of plan-specific information (e.g. required posting of plan materials, including transition plans and exception and appeals processes on plan websites and/or CMS website)
  - broader language access for non- and limited-English speakers
  - greater availability of alternative formats (e.g. for individuals with limited/no sight)
- Enforce existing pharmacy access requirements for Part D plans, especially in rural areas, or provide alternatives

IV. CONCLUSION

Medicare beneficiaries deserve a prescription drug benefit that they can understand and easily access. While many individuals are successfully getting their prescriptions filled and there have been some improvements in data issues and Part D plan responsiveness, many problems encountered by Part D enrollees will not go away without further attention and intervention.

Thank you for the opportunity to provide these comments. For more information, please contact CHA. Respectfully submitted by:

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MR. DEAL. Thank you. Ms. Rawlings.

MS. RAWLINGS. Thank you. Chairman Deal and other distinguished members of the committee, thank you for the invitation to address you today. My name is Susan Rawlings and I am President in charge of Senior Services for WellPoint, Inc. and that is the parent company of Blue Cross Blue Shield of Georgia, Indiana, and Maine. The majority of my career experience has focused in Medicare programs and retiree health plans that deliver products, programs, and services that meet the needs of our senior and disabled populations.

I am here today to talk to you about Part D implementation, but I would like to first start off by saying that for those WellPoint customers and pharmacists that we have not been able to serve within our own normal standards, we apologize. We are not discouraged, though. We are working diligently day and night and are making progress, which I will share with you today.

Prior to the launch of Part D we provided access to care for over one million Medicare members and we continue this tradition with the new

Medicare Part D benefit and we offer the new prescription drug benefit through our Medicare Advantage prescription drug plans, or MAPDs. We also have three regional PPOs, or the new program available through the MA, and they have the Part D prescription drug with them. We also offer stand-alone prescription drug plans in all 34 regions. WellPoint now contracts with 98 percent of rural, urban, and suburban pharmacies across the nation and our network continues to grow. We currently have an estimated 1.2 million Part D members, and approximately 60 percent of those are the auto-assigned dual eligibles.

Through the end of February, or February 27th, to be specific, we have already processed about 7.2 million prescriptions. WellPoint is fully committed to supporting effective implementation of Part D for all Medicare beneficiaries together with our partners at CMS. Our highest priority is to make sure seniors and disabled Americans are getting their prescription filled on a timely basis and are paying no more than they should. We are paying special attention to the transition to Part D for dual eligibles, especially those missed in the auto-enrollment process.

The facilitated enrollment program was created for just that purpose, to be a safety net for those dual eligible beneficiaries who were somehow missed in the auto-enrollment. WellPoint is the CMS contractor for this program. The process that was created allows the pharmacist to submit a claim for a prescription for a non-enrolled dual eligible person and enables the beneficiary to leave the pharmacy with their prescription. Everything the pharmacist needs to know about the process is written on a standard instruction sheet and has been provided to independent pharmacies, chains, and the pharmacy associations. If a pharmacy follows the steps described on the sheet, the dual eligible will be enrolled in a WellPoint plan and can immediately access their new drug benefits.

The pharmacy is a key partner in the program overall and especially in making this particular element work effectively and efficiently. They are responsible for verifying the eligibility of this individual when they are at the pharmacy and what that means is looking at their card, the Medicare card with their number on it, and they also are required to enter appropriate and minimal information into the system like the name, address, and birth date and a valid Medicare number in order for the process to work effectively. These modest requirements promote faster prescription processing and acts as important safeguards that protect pharmacists, plans, and CMS from potential abuse of the system.

This process is, in fact, little different than the process used to bill any public or private plan in the pharmacy and I can tell you it is working. As of February 27th, we have processed approximately 1.2 million claims through this system in every State in the country and that has enabled about 120,000 people to get their prescriptions and refills

now, in the second month. This unique program on the facilitated enrollment system between CMS and WellPoint, having served almost 120,000 people for two straight months, is by almost any measure a success. We are quite proud of it.

I would like to highlight a number of proactive steps we have taken, however, to help all Medicare beneficiaries around the country. Like my colleagues on the panel, we faced a number of challenges as we have moved through this in handling the service for our pharmacists and our members. We increased our staffing in our call centers, both in our pharmacies and our beneficiary call centers; we have added significant technological capability to expand capacity and to streamline our processes. We voluntarily extended our formulary transition rules from 30 to 90 days beginning January 1st before CMS asked us to and we have extended the facilitated enrollment prescription quantities from an allowed 14 days in early January to 30 days in mid-January, so we have been filling a full month there.

We have enhanced our communication efforts using multiple strategies with pharmacies and pharmacy associations, and these steps are working. We have a lot of steps left to take, but we are seeing significant improvements. For example, in our beneficiary call centers, our average speed to answer how long it takes us to answer the phone has improved; over 80 percent as compared to the first couple of weeks of January.

I would like to take this opportunity to recommend some additional strategies that CMS might consider to further improve the Part D implementation process and we very much appreciate their efforts to work with us collaboratively on these recommendations. First, to continue aggressive efforts to provide correct, accurate eligibility information. We have seen significant improvement from the beginning of January, but there is still more to do. Resolving this single issue will accelerate the pace at which the overall program is functioning smoothly.

And second, clarify that beneficiaries who choose to switch plans and enroll after the 15th of the month may not have their enrollment materials before the first day of the following month just due to data processing. This would help alleviate confusion among beneficiaries, including those for whom the data files may not yet correctly indicate their eligibility for the low-income subsidy.

In conclusion, I would like to say the Part D program is already making a big difference in the quality of life for many Medicare beneficiaries. We share the concern for beneficiaries expressed by many stakeholders, including this subcommittee, but I also want to acknowledge that this unprecedented public/private partnership between our industry, pharmacies, beneficiaries, and CMS brings together the

talent and determination necessary to solve these problems. Thank you and I would be happy to answer your questions.

[The prepared statement of Susan Rawlings follows:]

PREPARED STATEMENT OF SUSAN RAWLINGS, PRESIDENT, SENIOR SERVICES, WELLPOINT, INC.

Introduction

Chairman Deal, Representative Brown, and distinguished members of the Subcommittee, thank you for the opportunity to discuss implementation of the Medicare Part D Prescription Drug Benefit and the unique role that WellPoint's Facilitated Enrollment process is playing to address the challenges related to the transition of full-benefit dual eligibles to the Part D program. Facilitated Enrollment is functioning as an additional layer of protection to help fulfill the nation's promise to Medicare beneficiaries with special needs.

I am Susan Rawlings, Senior Vice President and President in charge of Senior Services for WellPoint, Inc. WellPoint, Inc. is the largest publicly traded commercial health benefits company in terms of membership in the United States. WellPoint is an independent licensee of the Blue Cross Blue Shield Association and serves its members through Blue Cross and Blue Shield plans in fourteen states and UniCare.

My career has been focused on Medicare programs, retiree health and applying the principles of geriatric medicine. At WellPoint, I am building on my experience by developing products, programs and services that meet the needs of our senior and disabled populations; for example, a key focus of mine over the last year has been the planning and application processes associated with the participation of WellPoint companies in the new Medicare Part D program. I am also continuing my efforts to broaden the understanding about older adults among multiple stakeholders. I believe that greater insight will be required to ensure that the health care system and the Medicare program are well prepared as the baby boomers age.

WellPoint Participation in Part D Prescription Drug Benefit Program

WellPoint has a long history of providing services to Medicare beneficiaries, including offering Medicare supplemental insurance and Medicare Advantage programs. As of 12/31/05, we were serving over 1 million beneficiaries in these programs across the country. Prior to the launch of Part D, we offered the interim prescription drug card. We have continued that tradition with the new Medicare Part D program. We offer the prescription drug benefit through our Medicare Advantage-Prescription Drug Plans (MA-PDs) in several regions, including the newly available Regional Preferred Provider Organization (PPO) in three regions, as well as stand-alone Prescriptions Drug Plans (PDPs) in all 34 regions, encompassing the 50 states and the District of Columbia. WellPoint offers three benefit plan options, enabling Medicare beneficiaries to choose the benefit plan that best meets their individual medical and financial needs. The formularies that support these products are consistent across the country. Our formulary designs meet or exceed the minimum requirements established in the law. Our pharmacy network is made up of 56,437 pharmacies nationwide, representing 98% of available retail pharmacies.

WellPoint is pleased to report that we have an estimated 1.2 million Part D members, of which approximately 60% are auto-assigned dual eligibles. To date, we have processed an estimated 6.5 million prescriptions of which approximately 1.2 million were processed through the Facilitated Enrollment program.

WellPoint Commitment to Part D Success

WellPoint is committed to supporting the effective implementation of Part D for all Medicare beneficiaries. We are focused first on making sure that these people get the prescriptions they need filled timely, and then resolving issues and problems so that all of our Part D members have a good experience when they go to the pharmacy. The transition to Part D for dual eligibles, and particularly those that were missed in the auto enrollment process, was not flawless and should have been easier for them. WellPoint shares the concern for the beneficiaries, and the frustration of pharmacists, elected officials, advocates, the States and CMS, *but we are not discouraged.* WellPoint's primary goal is to ensure that beneficiaries receive all the benefits of their health coverage, including access to prescription drugs, in a timely and beneficiary-friendly manner. We are doing everything in our power to make the transition a success and believe that progress is being made.

As all of the stakeholders work to improve the transition and implementation of this program, we must all keep in mind the tremendous value of adding a comprehensive prescription drug benefit to the Medicare program. Millions of seniors will not only see cost savings, but true improvements in their quality of life. The mindset at WellPoint is to focus obsessively on enabling seniors and disabled beneficiaries to receive their prescriptions, even when they were not initially assigned a plan. The recent report that nearly 25 million now have prescription drug coverage is not just great news, but reminds us that we must keep our full attention on resolving barriers to service. As Part D members begin using their new prescription drug coverage, the confusion in the marketplace will abate and a solid foundation for the Part D program will begin to take hold.

Recognizing Dual Eligibles As a Vulnerable Population

Continuing to improve the enrollment process is especially critical for the 6.3 million dual eligibles who often have more health care needs than other Medicare beneficiaries. Many dual eligibles live with chronic conditions that require multiple medications. They may have physical or cognitive disabilities, including mental health illness and Alzheimer's disease. They may suffer from diabetes or HIV/AIDS, and they may live in a nursing home. We provide services to dual eligibles facing cultural, linguistic and literacy barriers.

A "Customer First" Approach to Problem-Solving

"Customer first" is a core value at WellPoint. Our number one priority for this new drug program is that each beneficiary leaves the pharmacy with their prescriptions filled at the appropriate cost to them. For this reason, WellPoint is committed to shielding beneficiaries from complex work-around solutions and shielding pharmacists from unavoidable back-end reconciliations.

The level of collaboration among CMS, plans, pharmacies and other stakeholders is unprecedented. Continuing to improve on the progress we've made requires maintaining this collective effort. A shared approach to problem solving is the essential ingredient for making this new program work for all beneficiaries. Stakeholders are stepping up to the plate and accepting mutual accountability for meeting the challenges and ensuring the success of the Part D program. When all parties are bound by a common interest in putting the beneficiary first, an environment is created that allows for constructive criticism and open dialogue. The results being timelier implementation of the steps needed to achieve a smooth transition, faster identification of new issues, and smarter problem resolution.

Facilitated Enrollment Program: A Pharmacy Point of Service (POS) Solution

In early November, 2005, CMS approached WellPoint to develop a pharmacy-based solution to ensure that any dual eligible who was not auto enrolled would still get a needed prescription filled. WellPoint was ideally positioned for this role because we were the only company offering a plan with a premium below the low-income benchmark in all fifty states. On November 21, 2005, WellPoint signed the contract to become the "Facilitated Enrollment", or "Point-of-Service" (POS) vendor, for CMS. We agreed with CMS that no dual eligible, who are among Medicare's most vulnerable beneficiaries, should experience any gaps in coverage.

Once the contract was signed, WellPoint began a massive effort to operationalize the Facilitated Enrollment process in time for a January 1st effective date. A successfully designed safety net program would require executing many tasks related to claims administration, staff training, outreach and education, and other core areas of operation in both our health plans and our PBM. WellPoint was particularly focused on communication strategies, recognizing that working jointly with CMS to educate pharmacists would be critical to their use of this new process.

The Facilitated Enrollment process makes enrollment possible in those situations where a full benefit dual eligible visits the pharmacy and the pharmacist discovers that the individual has not been auto-enrolled into a Part D plan. With special facilitated enrollment, a dual eligible is enrolled into a WellPoint plan and can immediately access their Part D prescription drug benefits. A beneficiary can, however, also opt out and select a different Part D plan at any time. Pharmacy associations, chains and individual pharmacies have been provided information describing our Facilitated Enrollment solution.

The Facilitated Enrollment process is straightforward and consistent with putting the dual eligibles first: establishing a minimum threshold for proving Medicaid and Medicare eligibility in order to reduce the burden on the beneficiary. Let me describe the steps that a pharmacist can follow on behalf of a dual eligible that visits the pharmacy before he or she has been auto-enrolled but who has a Medicaid card:

1. The pharmacist bills Medicaid and the claim is denied.
2. Pharmacist checks for Medicare eligibility by one of the following:
   - Submitting an E1 query into the TROOP facilitator;
   - Calling 1-800-MEDICARE;
   - Requesting to see a Medicare card;
   - Requesting to see the Medicare Summary Notice (MSN); or
   - Requesting to see a letter from SSA stating that s/he may be eligible for Medicare.
3. If the pharmacist is unable to verify enrollment in a Part D plan through these mechanisms, she/he provides the prescription drug to the beneficiary at the $1/$3 co-payment levels and bills a special WellPoint account which WellPoint has provided on its payer sheet to pharmacists.

At WellPoint, the claim is flagged as being outside its normal claims process in order to prevent it from being rejected and then the claim is paid. If the pharmacy is not contracted with WellPoint, the pharmacy is sent special instructions to establish the mechanism for payment. WellPoint also flags this individual for CMS's vendor, Z-Tech, to verify their full dual eligibility status. At this point in the process the dual eligible is enrolled in a WellPoint plan, (but can always opt out and choose a different plan later). If Z-Tech confirms the dual eligible was previously enrolled in another Part D plan, WellPoint still pays the pharmacy and works directly with that plan for repayment. This approach is consistent with our principle of shielding pharmacies from back-end reconciliations.

The pharmacy is responsible for verifying the individual's eligibility for Medicare and Medicaid at the point of sale. As mentioned above, this is done through reviewing the Medicare and Medicaid cards or paperwork. This is a critical step in the process. The pharmacy is a key partner in caring for these duals, and drugs should be dispensed only to those eligible for the program. Although the pharmacy is responsible for verifying Medicaid and Medicare eligibility, the Facilitated Enrollment program only requires the pharmacist to enter appropriate, minimal information such as name, address, birth date and a valid Medicare number into the processing system. This requirement, in effect, streamlines the electronic edits at retail and mail to facilitate more rapid prescription processing. At the same time, the minimal data provided acts as important safeguards that minimize risk exposure to pharmacists and potential abuse of the program.

Additional Proactive Steps To Support Implementation Goals

Based on our experience with launching new programs and serving seniors and disabled beneficiaries, we planned for a higher call volume and a longer average call length that we thought would be appropriate for this program. However, like other Part D plans, our estimates of the difference in magnitude fell short; for example, we experienced calls lasting more than twice as long and call volume nearly 50% higher than we predicted. Beneficiaries and pharmacists were negatively impacted, experiencing lengthy hold times and busy signals. Some abandoned their calls in frustration. Overall electronic eligibility challenges across the program, particularly in early January, also created additional volume as pharmacies wanted to discuss eligibility over the phone.

WellPoint staff has worked collaboratively with CMS, pharmacies, industry trade groups, etc. to resolve the issues facing the program. We have been working literally day and night to fix these problems, as our first priority is that Medicare beneficiaries get the prescriptions they need on a timely basis. Many of the issues facing the program are systemic and data related and are being aggressively worked by industry and CMS workgroups. We must continue this collaborative work across the industry and with CMS – it is improving daily, but there is much more to do.

To improve our own service levels, some of the most effective mid-course corrections we have taken include:

- Increasing staffing as quickly as possible. We have already increased Part D staff from 455 people at January 1 to 545 at January 31. At the end of February we have nearly doubled our staff, with 900 trained people serving Medicare beneficiaries and pharmacies.
- Extending the hours of operation daily and to seven days a week.
- Adding additional T-1 lines in the PBM to speed up phone service and reduce busy signals.
- Providing connectivity and availability to interface with CMS on a 24/7 basis.
- Implemented internal procedures to address urgent situations as they arise.

Recognizing that our rapid response must also include strategies that assist Medicare beneficiaries and our pharmacist partners, we have also implemented the following:

On Behalf of Beneficiaries

- Voluntarily extended our formulary transition rules from 30 days to 90 days beginning January 1st prior to CMS mandating such a change for all health plans.
- Extended the Facilitated Enrollment prescription quantities from an allowed 14 days to 30 days.
- Increased beneficiary education to inform them about any changes they may experience during the transitional drug period.

- Contracted with outside vendors to accelerate information gathering from Part D program applicants to complete applications. When possible, information is obtained from external data sources to expedite automatic completion in order to minimize contacting beneficiaries directly.

On Behalf of Pharmacists

- Adopted an inclusive network development strategy to contract with a range of pharmacies, including independent and rural pharmacies, to increase pharmacy access to network advantages and to enhance beneficiary access to affordable prescription drugs.
- Enhanced outreach by constantly communicating with pharmacies through fax blasts, weekly conference calls with independent pharmacy associations (e.g. National Association for Independent Pharmacies and other independent chain groups) and chain drug stores (e.g. National Association of Chain Drug Stores and smaller work groups formed from major chains), and individualized calls to reach as many pharmacists as possible about Facilitated Enrollment.
- Engaged in active training through our PBM on the Facilitated Enrollment process for pharmacists when they call in.
- Provided direct technical assistance to pharmacies and their vendors if necessary to address software issues.

In brief, WellPoint has developed multiple mechanisms to eliminate the obstacles that interfere with dual eligibles receiving their medications and to ensure that pharmacists can serve their Medicare customers according to their own high service standards, while receiving timely and accurate reimbursement.

Customer Service Improvements: Progress To Date

Improvements Benefiting All Members and Pharmacies. Our customer phone service has not yet reached normal levels, but it is improving. For example, in our beneficiary call centers, our average speed to answer and our abandonment rates have improved by over 80% as compared to early January.

Facilitated Enrollment Results. As noted previously, WellPoint's Facilitated Enrollment program has processed approximately 1.2 million claims, enabling an estimated 240,000 beneficiaries to receive their prescriptions. As we monitor Facilitated Enrollment, we are finding that the process truly operated as a "safety net" in response to data and transaction issues. The good faith behind this program has also created an incentive for non-network pharmacists to join our network and enjoy faster payment through electronic reimbursement. Overall, early skepticism regarding receiving payment seems to be yielding to an increased comfort level among pharmacists as evidenced by the increased claims volume.

Remaining Challenges and Recommendations

A number of challenges remain that require all stakeholders to work in partnership to establish a high performance Medicare Part D program that will make a difference in the lives of so many older and disabled Americans. With enrollment growing daily, we must not only invest our time and energy, but also capitalize on the new relationships and knowledge gained from this experience. Addressing issues related to dual eligibles and the Facilitated Enrollment process is a top priority for WellPoint. These more vulnerable Medicare beneficiaries are also at the forefront of CMS's efforts as well. For this reason, I would like to take this opportunity to recommend some additional administrative strategies that CMS, as our partner, might take to further optimize the Part D implementation process, benefiting all constituencies – beneficiaries, pharmacists, CMS and health plans. Our recommendations include:

1. ***Intensify efforts to provide correct, accurate eligibility information***. Many of the current challenges associated with Part D implementation stem from the need for clean, accurate eligibility data. Resolving this single issue will accelerate the pace at which the overall program is functioning smoothly. Improving data accuracy and the process for updating and validating the CMS eligibility file will ensure claims are paid by the correct plan and the beneficiary is charged the correct cost sharing amount, as well as eliminate the incentive for pharmacists to substitute the phone or the Facilitated Enrollment process for the more appropriate E1 transaction. CMS and the industry have made substantial progress since early January.

2. ***In order to avoid confusion and frustration for beneficiaries, CMS should clarify that beneficiaries who choose to switch plans and enroll after the 15th of the month may not have their enrollment materials before the first day of the following month.*** Allowing those beneficiaries that enroll in or switch their Part D plan prior to the 15th of the month to be enrolled with their new plan on the first day of the following month would help address this issue. CMS should likewise educate beneficiaries accordingly about the importance of enrolling prior to the 15th of the month. It is important to note that most states already use a similar approach with respect to dual eligibles applying for Medicaid eligibility. This recommendation would go a long way towards avoiding disruption for those Medicare beneficiaries for whom the data files may not yet correctly indicate their eligibility for the low-income subsidy.

3. ***Increase Pharmacy Outreach to Create One-Stop Shopping For Help.*** CMS has been conducting educational outreach to pharmacies and we commend the efforts – and we recommend it continue in earnest. Additionally, we recommend that CMS train their call centers to handle additional pharmacy related calls, particularly when pharmacies call about the Facilitated Enrollment process. Currently, CMS refers pharmacists to our call centers when contacted about the Facilitated Enrollment process or edit questions. Since the process is not complicated, we would suggest that CMS directly provide instruction to pharmacies on how to process a Facilitated Enrollment claim during the initial call or, as we add the editing of the Health Insurance Claim Number (HICN), share the reason for the Facilitated Enrollment edit. Pharmacists would appreciate the timely assistance and many would use the information to trigger the FE enrollment process without having to make a second call to WellPoint. We would be pleased to work with CMS to train their staff.

Conclusion

The January 1st effective date for the launch of the Medicare Part D program brought with it a surge of business operations activity and customer service requests. In preparation, WellPoint did extensive advanced implementation planning and outreach, knowing that the program was complex, with many moving parts that had to work in synchrony. Our hope was that we had anticipated the major barriers that might arise as seniors navigated the enrollment system and pharmacists attempted to fill prescriptions. While it was not possible to foresee all the challenges that this enormous undertaking would pose, it is in WellPoint's DNA to be a part of the solution. We will continue to strive to get past the hurdles because the Medicare Part D prescription drug program is worth it.

Thank you for your time. I would be happy to answer any questions you may have.

MR. DEAL. Thank you very much. We have a reduced audience up here now. Ms. Walsh, let me start with you. First of all, with regard to the dual eligibles who were automatically enrolled. Did the State do that? Was that a State decision that automatically enrolled them in the plans or how was that handled?

MS. WALSH. We have drugs for the elderly program that we were going to intelligently assign these people into plans so that they would have 90 percent or more of their drugs covered and we certainly didn't want to leave our dual eligibles, who are more frail and more poor than our ESPAP members, without that kind of intelligent assignment. So we sent a proposal to CMS in October that wasn't acted upon until late December with approval from CMS. We were told by CMS you can enroll in a plan on the 30th and have coverage on the 1st, so when we sent our files to the plans on the 20th, we did expect them and had assurances from the plans that they would honor our enrollment for January 1st and many of them did honor the enrollment. What happened primarily was they didn't have that low-income subsidy indicator.

MR. DEAL. Right. So your primary problem has been getting that low-income subsidy built into the formula?

MS. WALSH. Yes, it really has, yes. Yes.

MR. DEAL. All right. Is progress being made on that?

MS. WALSH. Oh, every day. Things are getting better along those lines, but I think, for some reason, we have one particular plan in Maine that has the bulk of our people and they still are missing thousands and thousands of low-income subsidy indicators.

MR. DEAL. And where does that information have to come from, CMS?

MS. WALSH. Yes.

MR. DEAL. Okay. With regard to the money that the State has expended, my understanding is that a part of that money is the differential between what the traditional Medicaid program would have paid and what the plans themselves may have paid. You have paid based on what the Medicaid would have paid the pharmacists for the drugs and you are part of the model, so that differential will be made up to you. Is that your understanding, as well?

MS. WALSH. Yes, and I am glad you brought that up because I was hearing Dr. McClellan's comments earlier about that and I wanted to say the State of Maine and many other Medicaid programs typically reimburse pharmacies better than private insurance companies. What we do is we negotiate aggressively with pharmaceutical manufacturers so the net price or the net cost to the State, under the Medicaid program, is lower than what you are getting under Medicare Part D.

MR. DEAL. Is that because of the rebates you are talking about?

MS. WALSH. Because of rebates, that is correct.

MR. DEAL. Okay. Mr. Lipshutz, with regard to the problems that you have outlined, are you seeing progress being made in terms of eliminating some of these problems that initially presented themselves on time problems?

MR. LIPSHULTZ. The call volumes to the State SCHIP program, the HICAPs, has diminished somewhat, but it is my understanding that is in large part because the calls were primarily coming from dual eligibles prior to the State stepping in with that emergency coverage.

MR. DEAL. Right. I think once we get the dual eligible situation ironed out as nearly as possible, much of the complaints will actually go away. Mr. Paul, would that be your assessment, as well?

MR. PAUL. That is correct. We have noticed a significant reduction in the call volume since the beginning of January.

MR. DEAL. And Ms. Rawlings, I assume you indicated that your time is reduced by 80 percent, I think, is what you said the time for waiting?

MS. RAWLINGS. That is correct, it is. Yes.

MR. DEAL. Okay. So you know, and Mr. Ettienne, we want to extend to you the same expression I did to the representative, Mr. Song, from the Community Pharmacists, and that is the role that your chain pharmacy people have played in making this transition possible, too. You really truly have been heroes at every level because you are on the front lines. We, by necessity, had to put you there and I want to thank you for that. Do you feel like we have made significant progress and do you feel like that we have gotten over most of the rough spots so far?

MR. ETTIENNE. I think we have made significant progress in the process. I think, like with any large implementation, you expect hurdles at the front of it. Moving forward in the stores, the pharmacists are indeed much happier today when compared to January 1st.

MR. DEAL. Right. Well, I think the suggestion that Ms. Rawlings made about that if you are going to change plans, you need not expect that you can come in the last day of the month and then the first day of the next month that somebody is going to have your information there and there is not going to be a problem. I do think that that is the information that we need to get out with regard to swapping plans, is to be prepared for a little bit of lag time. We do live in the information age, but we don't live in that kind of information age, especially when you are talking about millions of people.

Well, that will be all that I will ask you. I do appreciate all of your patience, again, your presence here today and I think this will be an ongoing discussion that we will have and hopefully the complaints that we have heard will not be the same complaints that we hear the next

time. Hopefully, we will address those and in anticipation of those, we hope that you will continue to share the things that you see that need to be corrected with CMS or with us and as much as possible, we will try to address those. Mr. Pallone, you are next.

MR. PALLONE. Thank you. Those of you who were here when Dr. McClellan spoke know about my concern with this whole appeals process and prior authorization and what is going to happen after the transition period is over with. So I wanted to start by asking Mr. Lipshutz about the transition policies and also the appeals process. We have heard a lot of instances where Medicare drug plans failed to honor their transition policies and where they were, of course, supposed to give beneficiaries a one time fill for prescriptions not on a drug plan's formulary without other barriers like step therapy or prior authorization.

According to calls received by the American Psychiatric Association, during the first nine weeks of Part D, in 44 percent of the cases that came to their attention, continuity of care was disrupted for vital medications covered by CMS's all, or substantially all, guidance because patients were unable to obtain needed medications, particularly serious for people that have mental health problems. And it seems to be, in spite of what the Bush Administration is telling us, something is not working. Dr. McClellan told us everything is fine but here is an example of where the Administration has failed dismally, in my opinion.

So I just wanted you, Mr. Lipshutz, if you could comment on what is happening to individuals with mental illnesses and maybe provide examples of whether or not things are really fine, as the Administration would have us believe.

MR. LIPSHULTZ. I think the example that I highlighted of Mr. H., the 23 year old Medicare beneficiary who was stabilized on anti-psychotic medication is quite illustrative in that he is an individual who was stabilized on a dosage amount of a particular medication that was amongst the required six categories of drugs that all plans must cover. He found, or his family found, that while the drug was covered as required under Medicare rules, that he was unable to access the dosage amount that his psychiatrist had worked very hard to put together that worked for him. I think that experience is echoed over and over.

In response to your questions about the transition plans and the exceptions and appeals processes, at the outset, CMS put fairly lax requirements on plans about the need to provide transition policies. In fact, initially, plans were not required to even provide a first fill for prescription drugs. They could either provide a first fill or contact enrollees to sort out whether or not they needed any prescription drugs that were not on the formulary to try to work with them to change their prescription drugs.

Since then, CMS has moved in the right direction by requiring more out of plans as far as transition first fills, but obtaining what these actual policies are from plans and how they are applied has been very difficult, from an advocate standpoint, to try to get that information from the plans, and we are hearing that lots of individuals are having trouble actually accessing that transition policy that CMS has requested plans to follow. In large part, that happens at the pharmacy in problems with information exchanges between pharmacies and Part D plans. A lot of pharmacists are unaware of the obligations they have to fulfill or are unwilling to honor transition plans.

MR. PALLONE. And then that once a transition process, you know, or that period is over, then we are going to have more problems, I think, with appeals and prior authorization. There have been a number of reports where drugs that are on the formulary have high quota sharing and as a result, they are unaffordable and beneficiaries are faced with these exceptions and appeal processes and cumbersome prior authorization. Can you talk a little bit about how these things are impeding beneficiary access to needed medicines or making excess work for pharmacists or doctors? You know, I mentioned before with Dr. McClellan about having some kind of standardization. Do you think it would be wise to adjust cost sharing requirements that standardize and simplify exceptions or appeals? I mean, is there more that can be done in that regard?

MR. LIPSHULTZ. I think that simplifying the exceptions and appeals process along with the utilization management tools would go an awfully long way towards helping beneficiaries get their prescription drugs. A number of doctors have informed HICAP programs and beneficiaries that they are simply not going to follow the exceptions and appeals process because they have to deal with different plans and different policies for each Part D plan. Part D plans have a good deal of discretion in how they establish their exceptions and appeals processes. They can determine whether or not they accept requests over the phone or in writing, and they can set the amount and type of evidence that physicians must provide to the plans in order to determine medical necessity.

One medical group in northern California has established a policy whereby it will require all of its physicians not to assist their patients with the exceptions and appeals process unless the patients have scheduled office visits with the doctors because otherwise the doctors are uncompensated for that time. But if a beneficiary needs a drug in a quick amount of time, that is going to be very difficult for a beneficiary to do, to try to schedule a doctor's visit and go in and get that drug. Standardization of the exceptions and appeals process, including standard forms that were used by all the plans would help both

beneficiaries and their prescribing physicians access need prescription drugs.

MR. PALLONE. All right, thank you. Thank you, Mr. Chairman.

MR. DEAL. Thank you. Mr. Buyer.

MR. BUYER. Mr. Ettienne, for the purpose of open disclosure, did I pronounce it correctly? No? How do you pronounce your name?

MR. ETTIENNE. It is okay.

MR. BUYER. No, no, no.

MR. ETTIENNE. Ettienne.

MR. BUYER. For purpose of open disclosure, my daughter, Colleen, is a pharmacy student out of Purdue and has worked for CVS for three years.

MR. ETTIENNE. Okay.

MR. BUYER. So I got to live through this, through my daughter, because she was working on January 1st and January 2nd and who do you think she came home and gave hell to?

MR. ETTIENNE. Daddy.

MR. BUYER. Daddy, yes. And so it was pretty unfortunate, some of the glitches that, in fact, that occurred, especially on the dual eligibles. I don't think there should be any excuse right now with regard to our long term care dual eligibles. There shouldn't be any excuse, yet I have spoken with three different pharmacists in Indiana, three different sizes, small, medium and large. Lafayette, Indianapolis, Bedford. I didn't go to CVS or Walgreens or any of those, these are independent pharmacists. The one in Bedford, in particular, said that about 10 percent of his claims are still this problem with the dual eligibles and the long term care and the deductibles and that is pretty sad. Is CVS, or are you still seeing that problem?

MR. ETTIENNE. We have seen a significant reduction in the number of problems that we have had from January 1st to today. I can't say that there aren't problems, but the number of problems that we are seeing now is dramatically less. I think the advantage that we have had is the preparation. We have a tremendous team in the corporate office and they are working through a lot of the issues and getting that information to the pharmacists in an effort to help them process the claims.

MR. BUYER. One thing I have learned here in Congress, every time we try to make an effort on a legislative front, there are always unintended consequences, so by example, when we changed the liability with regard to the manufacturing production of small aircraft to bring the industry back to the United States, so we changed the products liability rules, okay? So it is kind of a good thing. Wow. So we had this incredible impact upon what? The exodus of technical skills out of the military into the private sector, the loss of pilots out of the military, right,

because what did we do? We have now spawned a new industry because we brought back the small plane business in America. I am talking about small plane meaning jets, you know, and wonderful aircraft, but we brought that because we made a change in the law.

Likewise, we now create a program whereby pharmacies are also experiencing an increase workload. You have an increase in workload because we have created a program whereby individuals can now access their medications, but what pain have we also now increased in the health system with regard to we were already short pharmacists and technicians? So is there some--I mean, give me a way ahead, a look ahead. I want you to help us here. Are we saying Steve, that we need to now be in communication with our pharmacy schools around the country, that we need to increase the positions because relative to demand, this is not going to work? If that increased by one-third, you have only got a certain supply of those pharmacists. Tell me what we have done to your life.

MR. ETTIENNE. We certainly have increased workload in the pharmacies. A greater supply of pharmacists is definitely a good thing for the industry. We know, I mean, we have seen in many States across the country where pharmacists are indeed in demand, but they are in short supply. If I were to attempt to look into the future, I would say hey, you know, this is indeed a good thing for the patient because we are getting people drugs that they didn't get prior. We do need to make adjustments to the program as designed to ensure that we don't have what you are describing; we don't have any kind of catastrophic events down the road.

I would say if you had some means of increasing the supply of pharmacists to deal with the work flow, by all means. We would be happy to step up and work with you in realizing that process.

MR. BUYER. I just encourage you today--you are going to be telegraphing this, hopefully, before we can see it and we, in turn, can be extremely helpful to the colleges and what their requirements are to open up these slots. I just want to do the look ahead. I want to be prospective, not reactive. So please, when you speak to your comrades, let me know, all right?

MR. ETTIENNE. We certainly will. We do need pharmacists, so by all means, you cannot wait for that process, just go right ahead. We will be happy to employ them.

MR. BUYER. All right, thank you.

MR. DEAL. Mr. Allen, you are recognized.

MR. ALLEN. Thank you, Mr. Chairman. I want to thank you for being here. I assure you all that though it may be late and the committee has thinned out a little bit, that your testimony is either being watched

now by other staff members or your testimony has been or will be read and we thank you very much for coming here because you do bring an experience that we don't get ourselves, obviously. I had a couple of questions. Ms. Walsh, I wanted to go back to Maine just for a minute. There are all these different plan choices and for some people this is a curse, not a blessing. It is too many. CMS auto-enrolled the dual eligibles, 6.4 million across the country, without regard to their diagnosis or their current drug regimen. Now, you took a different approach in Maine and I think you described that. You don't need to go back into that, but looking forward, I think it was Mr. Lipshutz who said California will have 10,000 dual eligibles a month coming into its system because people who are today on Medicaid, you know, obviously some of them become 65, they qualify for Medicare so they are covered and they have the same sorts of issues. Going forward, Ms. Walsh, what advice would you give CMS on how to deal with the ongoing dual eligible issue?

MS. WALSH. Well, I think enrollment into plans and eligibility are the two largest issues going forward and I think something CMS could do in the future is work more collaboratively with States up front. States typically, of their dual eligible, maintain current drug profiles for members. In Maine, we have built an algorithm and are able to recommend which plans people should be going into and I think one of the keys to working dual eligibles effectively through this Medicare Part D benefit is to really assign them to plans that have the best match for their drug benefit, especially because it takes six to eight weeks to get out of a plan and into another one.

MR. ALLEN. To get out of a plan--well, some people can't get out of a plan--

MS. WALSH. Some people are stuck there for a long time.

MR. ALLEN. About once a year, right?

MS. WALSH. Well, I think if you are a dual eligible, you have the option under Medicare to change your plan every month. It just really takes almost two months to get into a new plan, so if you have been randomly assigned by CMS into a plan and most of your drugs aren't covered, you have to wait almost two months to get into a plan where your drugs are covered.

MR. ALLEN. Okay. I would like to talk just a little bit, hear from, I guess Mr. Lipshultz. Maybe I will ask this of you. The virtues of simplicity. I mean, based on your experience, would a simpler plan be more usable, easier for seniors and the disabled to navigate than the current system? And if so, how would you suggest we go about it?

MR. LIPSHULTZ. Well, to use my mom as an example, and I would be the last to say anything disparaging about my mom, but she would not be able to figure this program out if it wasn't for my help, who has

studied the program quite a bit. I think the fact that there are a number of plans and in Los Angeles County you have 47 stand-alone prescription drug plans plus at least 20 Medicare Advantage prescription drug plans for almost 70 plans, the number of plans, the fact that you need to take a look at what is on the formulary. Then once you see what is on the formulary, you have to find out how much you pay for your drug, whether or not that drug is subject to utilization management, whether or not your drug plan has a network of contracting pharmacies and the fact that there is such variance amongst the plans I think would lend itself to more standardization and I would encourage the committee to take a look at the debate around standardizing the Medicare supplemental insurance programs back in the early 1990s which made them a lot more understandable and easy to use. Definitely more standardization would help beneficiaries help navigate this benefit better.

MR. ALLEN. Okay. Mr. Chairman, I have just one concluding thought here. I want to come back to this question of savings. Mr. Paul mentioned savings, and Dr. McClellan mentioned savings. I get very worried about our talking about savings in the aggregate which covers up a lot of things. I mean, for example, I think Mr. Paul, you said there were real savings enjoyed by millions. You may be right. All I know is that the big question is compared to what? We would agree that for people who had no prescription drug coverage in the past and now they have a plan, probably that plan works unless they don't have very much in the way of drug expenses and they are paying more in premiums than getting back in cost. But compared to Medicaid, it is not so clear. Compared to those people who are on the pharmaceutical companies' own free or reduced cost plans, it is not so clear. Compared to some of the State programs like Maine had, it is not so clear. So I just, this is a pitch for a little bit of complexity here and how we think about because clearly all of us on this side of the aisle want those of our constituents who can benefit from this plan to get the benefit of the plan. On the other hand, we are still hearing from lots of people who are not very happy and the complexity is a part of the issue. And with that, I won't ask you all to comment on that. Probably enough has been said today, Mr. Chairman. Thanks for your patience.

MR. DEAL. Well, thank you, and I thank you for staying with us the whole time. Thanks again to all of you. Your comments have been made a part of the record, and your written testimony has been added. Obviously, there are differences of opinion, concerns, but all of us, hopefully, are working toward a mutual goal of making this work for the people of this country who are eligible for the plan. We thank you for what each of you play a role in making that possible. With that, the hearing is adjourned.

[Whereupon, at 6:45 p.m., the subcommittee was adjourned.]

RESPONSES FOR THE RECORD SUBMITTED BY THE HON. MARK MCCLELLAN, ADMINISTRATOR, CENTERS FOR MEDICARE & MEDICAID SERVICES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

OCT 13 2006

The Honorable Nathan Deal, Chairman
House Energy & Commerce Subcommittee on Health
2125 Rayburn House Office Building
Washington, D.C. 20510

Dear Chairman Deal:

Thank you for the opportunity to testify before the House Energy & Commerce Subcommittee on Health regarding "Medicare Part D: Implementation of the New Drug Benefit" on March 1, 2006.

Enclosed is the edited transcript and answers to questions submitted in writing after the hearing by Rep. Dingell, Rep. Davis, Rep. Pallone, Rep. Pickering, and Rep. Waxman. A similar letter has been sent to these members as well as Chairman Barton and Ranking Member Brown.

Your continued interest and support are essential for the Medicare and Medicaid programs' success. If you have any questions or need additional information, please do not hesitate to contact me.

Sincerely,

Mark B. McClellan, MD, Ph.D.
Administrator

Enclosures

The Honorable John D. Dingell
Questions for the Honorable Mark B. McClellan, M.D., PhD., Administrator
Centers for Medicare and Medicaid Services
March 1, 2006
Subcommittee on Health
Hearing entitled: "Medicare Part D: Implementation of the New Drug Benefit"

Thank you for your testimony at the hearing on March 1, 2006. I am interested in following up on how well Part D is working to provide beneficiaries with their medications. I am concerned that plans may use a number of so-called utilization management techniques to prevent patients from getting their medicines. These techniques include:

- Excluding a drug entirely from the formulary;
- Charging higher cost-sharing for certain drugs (by placing it in a higher, unaffordable cost-sharing category);
- Requiring prior authorization (or approval) from the plan before a beneficiary can get their medicine;
- Requiring patients to try a different medicine from the one they are currently taking, to see if it will work before they are permitted to fill a prescription for their preferred medicine (step-therapy); and
- Placing limits on the quantity of pills that may be received (i.e., only dispensing 30 pills in a month when the patient normally takes 60) or limits on the dosage or strength of the drug that will be covered.

Question:

In order to evaluate the program, please answer the following questions for the record:

(a) The total number of beneficiary requests for appeals under Part D that have been filed with private plans to date;

(b) The total number of beneficiary appeals by type including: medicine not included on the plan formulary, requiring a different medicine be tried before accessing the doctor-recommended drug (step therapy), limits on the number or dosage of medicine that is allowed under the plan, denials by plans of a medicine because the plan concludes it is not medically necessary to treat the patient's condition, or denials by plans of payment for a medicine because the beneficiary obtained the medicine through an out-of-network provider, etc.;

(c) The number of appeals by category of beneficiary (elderly, individuals with disabilities, dual eligibles, low-income subsidy, institutionalized individuals);

(d) The drugs most commonly appealed across all of Part D and also for each category of beneficiary;

(e) The disposition of those requests (how many were resolved in favor of the beneficiary, how many in favor of the plan) by type of appeal, category of beneficiary, and by drug;

(f) The number of appeals that are still pending/unresolved, and the number which have not been resolved within CMS's required time frames; and

(g) The number of appeals pursued to the next higher level.

Answer:

CMS is committed to providing information about plan performance to ensure beneficiaries can make informed decisions about plan selection. While we were unable to provide data regarding beneficiary appeals and exception requests at the time of this hearing, we subsequently released comprehensive appeals and exceptions data for January 1, 2006 through July 31, 2006. These data include the overall volume of reconsideration requests, including standard cases and expedited cases; the types of appeals received (i.e., utilization management disputes, off-formulary exception requests, cost-sharing disputes, tiering exception requests); the overall rate of reversals by the Part D QIC; reversal rates by appeal type; and the overall timeliness of reconsideration cases. The complete fact sheet that sets forth data in each of these areas is copied below, and also available on the CMS website at http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1972 .

FACT SHEET
PART D RECONSIDERATION APPEALS DATA

Part D Appeals Process

An appeal is the process by which an individual enrolled in a Medicare prescription drug plan (an "enrollee") may challenge a plan's coverage determination. Appeals begin with a request by a beneficiary (or their representative) for a redetermination by the plan. If the reconsideration response by the plan is not satisfactory for the beneficiary, the beneficiary may request a reconsideration by the Part D independent review entity (also called the Part D qualified independent contractor or "QIC"). Beneficiaries may subsequently appeal the independent review decision to an administrative law judge, the Medicare Appeals Council, and federal judicial review.

The following data summarizes and highlights some of the key data on reconsiderations since the inception of the Medicare prescription drug benefit program on January 1, 2006.

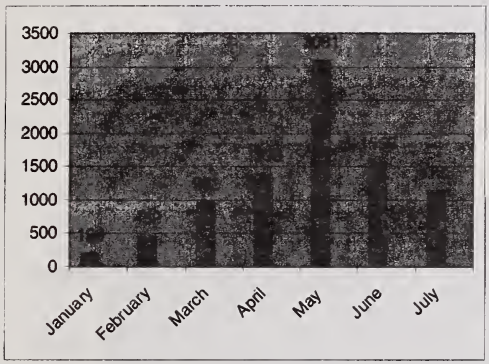
Reconsideration Volume

8,772 reconsideration requests were received from January 1, 2006 through July 31, 2006. [a] This represents a rate of 0.44 reconsiderations for each 1000 Medicare beneficiaries enrolled.[b]

Standard cases represented 90% of all appeals received and resulted in a rate of 0.40 standard cases for each 1000 beneficiaries enrolled.

Expedited cases represented 10% of all appeals received and resulted in a rate of 0.04 expedited cases for each 1000 beneficiaries enrolled.

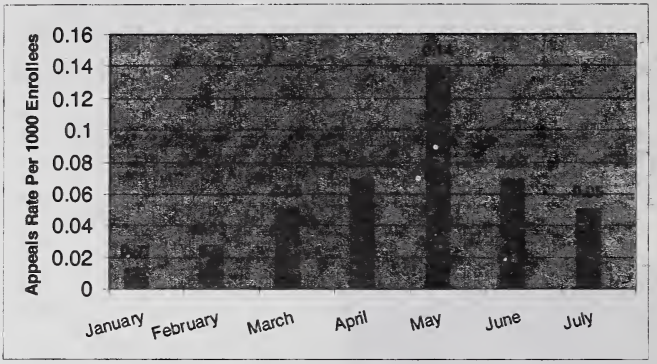
Number of appeals received by the Part D QIC by month:



[a] The Part C QIC received 12,281 appeals during this period. Note that all adverse Medicare Advantage plan decisions are automatically forwarded to the Part C QIC, unlike in the Part D program where the beneficiary must request the appeal.

[b] Aggregate numbers were calculated using the average enrollment over the 7-month period from January through July of 2006.

Rate of appeals received by the Part D QIC by month:[c]



Types of Appeals

Of the 8,336 appeals decided through July 31, 2006:

36% involved a drug utilization management tool dispute and represents 0.15 drug utilization appeals for each 1000 beneficiaries enrolled.

34% involved an off-formulary exception request and represents 0.14 off-formulary exceptions appeals for each 1000 beneficiaries enrolled.

26% involved a non-Part D drug (a drug that is statutorily excluded) request and represents 0.11 non-Part D drug requests for each 1000 beneficiaries enrolled.

2% involved a cost-sharing dispute and represents 0.01 cost-sharing dispute appeals for each 1000 beneficiaries enrolled.

<2% involved a tiering exception request and represents 0.01 tiering exceptions appeals for each 1000 beneficiaries enrolled.

<1% involved out-of-network pharmacy coverage.

[c] Monthly appeals rate was calculated using the enrollment at the end of each month.

Overall Reversal Rate

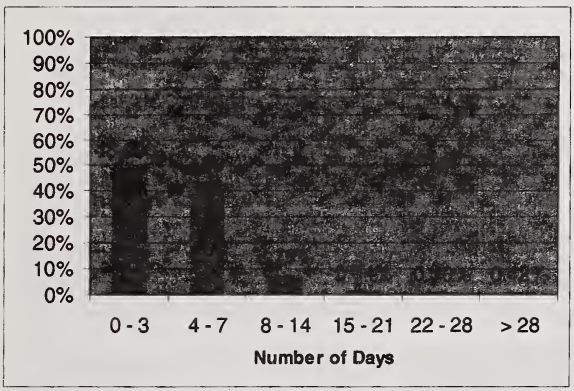
Excluding cases that were dismissed, withdrawn, or remanded (the Part D QIC did not have jurisdiction to make a substantive decision on the case) and cases involving non-Part D drugs, the Part D QIC reversed plan decisions in 42% of cases.[d]

Reversal Rates by Appeal Type[e]

Drug utilization management tool dispute	51%
Off-formulary exception request	31%
Non-Part D drug	15%
Tiering exception request	33%
Cost-sharing dispute	33%
Out-of-network pharmacy coverage	60%

Overall Timeliness of Reconsideration Cases

Distribution of decided appeals by process days for all reconsideration cases:



[d] In comparison, the reversal rate for Part A cases was 24% and for Part B cases was 39% for the same period. The reversal rate for Part C cases during this period was 13%. Note that the reversal rate for Part C is impacted by the fact all adverse Medicare Advantage plan decisions are automatically forwarded to the Part C QIC.
[e] Calculation of the reversal rate by appeal type excludes cases that were dismissed, withdrawn or remanded.

Question:

With respect to the instances where prior approval is needed from a plan before accessing a particular medicine, please provide:

(a) A listing of the different medicines (organized by class of drug, e.g., anti-depressants) subject to prior authorization or step therapy (or other restriction) across Part D;

(b) The number of cost-sharing categories used by plans and the placement of medicines in those categories, e.g., how many drugs subject to plan restrictions are charged the highest cost-sharing, how many are charged the next highest cost- sharing, etc.;

(c) A summary of the policies used by plans to determine how much cost-sharing is paid by the beneficiary when formulary exception is approved (e.g., do beneficiaries pay the lowest or highest cost-sharing available under the plan, does the plan have discretion for how much to charge, does this vary across plans?)

(d) The number of different prior authorization forms in use in individual plans and across all Part D plans;

(e) The evidence plans require beneficiaries or providers to submit in order to get a prior-authorization request approved and whether such evidence requirements are uniform across all plans or not;

(f) The means for determining whether the request for a medicine should be granted, and whether this standard varies across plans;

(g) The number of beneficiaries taking a medicine in the six "protected categories" of drugs who have been told that their medicine is not covered, or that it is covered, but in a high (and sometimes unaffordable) cost-sharing category, or that it is subject to some other restriction and the number of beneficiaries who have failed to access one of these needed medicines under Part D because of excessive cost- sharing imposed by their plan;

(h) The number of prior authorization requests that have been filed to date pertaining to a drug in one of the six "protected" classes;

(i) Any enforcement actions taken relating to Part D plans failing to comply with CMS guidance on access to medications in one of the six protected classes.

Answer:

Validated data necessary to answer all of these questions is not currently available. Formularies and formulary management practices vary across plans, subject to CMS-published guidelines reflecting two overarching policy objectives. First, Part D plan sponsors must provide access to

medically necessary Part D treatments and must not substantially discourage enrollment by particular types of beneficiaries. Second, plan sponsors are expected to use approaches to drug benefit management that are proven and in widespread use in prescription drug plans today.

As a condition of participation in Part D, sponsors must submit their plan formularies for CMS review and approval. CMS reviews plan formularies using a 13-step process, which considers covered drugs as well as utilization management techniques. The formulary guidelines describe 13 review checks to ensure that formularies meet all statutory and regulatory requirements. Those checks include:

1. Review of USP categories and classes (USP Model Guidelines)
2. Comparison with American Hospital Formulary System categories and classes
3. Two drugs per category and class
4. Review for USP formulary key drug types
5. Review of tier placement for all drugs
6. Review of widely accepted treatment guidelines
7. Review for 6 therapeutic categories or pharmacologic classes requiring uninterrupted access ("all or substantially all" requirement)
8. Review for common drugs used by Medicare population
9. Quantity limit review
10. Prior authorization review
11. Step therapy review
12. Insulin supplies and vaccine review
13. Long-term care accessibility review

If CMS reviewers find that a plan's formulary design in any one of these areas could substantially discourage enrollment by certain types of beneficiaries or otherwise violate Part D program requirements, that formulary will not be accepted and if unchanged, the plan is not eligible for a Part D contract.

In the case of the six therapeutic categories or classes of drugs for which plans must include "all or substantially all" available drugs, CMS has found plan sponsors are complying with the formulary guidance. Part D sponsors may not implement prior authorization or step therapy requirements that are intended to steer beneficiaries to preferred alternatives within these classes for enrollees who are currently taking a drug; but prior authorization may be used in order to promote safety, consistent with FDA clinical and safety guidelines. CMS has worked with industry partners to develop standardized prior authorization and appeals forms to facilitate consistency across plan sponsors.

Beneficiaries may request an exception to have a non-formulary Part D drug treated as on-formulary under a particular plan, or to access a particular drug on a plan's formulary at a more favorable cost-sharing level. An exception is a type of coverage determination request. All Medicare drug plan sponsors must have a timely and efficient process for making coverage determination decisions, including decisions on exception requests. Generally, plan sponsors must approve exceptions when they find that the drug being requested is a Part D drug, and that the on-formulary (or lower-tier) drug would not be as effective or would have adverse effects on the beneficiary, or both. These determinations are made in light of supporting information

provided by the member's doctor.

Plan sponsors must establish a "uniform plan level" of cost-sharing for non-formulary drugs approved through the exceptions process at the level of an existing formulary tier, in order to create certainty for beneficiaries with regard to cost sharing for such drugs. A Plan sponsor may establish its uniform plan level of cost-sharing at the level of any existing formulary tier (including the specialty tier if the drug would otherwise meet the requirements for the specialty tier, if applicable, if it does not exceed 25-percent of the actual costs of the drugs contained in that tier).

Question:

With respect to plan performance in terms of accessing medicines and beneficiary/provider use of the appeals, please list the top five plans in each State with:

(a) The greatest number of appeals filed (in each plan category);

(b) The fewest number of appeals filed (in each plan category);

(c) The greatest number of appeals resolved in favor of the beneficiary;

(d) The greatest number of appeals resolved in whole or in part in favor of the plan; and

(e) The greatest number of appeals not resolved within CMS-required time frames.

Answer:

CMS is committed to providing information about plan performance to ensure beneficiaries can make informed decisions about plan selection. While we were unable to provide data regarding beneficiary appeals and exception requests at the time of this hearing, we subsequently released comprehensive appeals and exceptions data for January 1, 2006 through July 31, 2006. These data include the overall volume of reconsideration requests, including standard cases and expedited cases; the types of appeals received (i.e., utilization management disputes, off-formulary exception requests, cost-sharing disputes, tiering exception requests); the overall rate of reversals by the Part D QIC; reversal rates by appeal type; and the overall timeliness of reconsideration cases. The complete fact sheet that sets forth data in each of these areas is copied above in response to your first question, and also available on the CMS website at http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1972 .

Question:

With respect to your oversight and enforcement of Part D plan activities, please answer the following questions:

(a) Has CMS initiated any corrective action, applied any sanction, or otherwise reprimanded any particular plan – including any warning letters – for its practices during the first two months of the Part D benefit program?

(b) How many complaints have been received to date pertaining to false, fraudulent, or otherwise misleading marketing or enrollment practices? Please provide the number of complaints and nature of each, as well as the general source (beneficiary, State, provider, etc.). How many of these complaints have been resolved?

(c) How many complaints have been received to date pertaining to other issues regarding plan conduct? Please provide the number of complaints, nature of each, and status.

(d) What are the top five plans in each State with the highest number of complaints and the top five plans in each State with the fewest complaints?

(e) What corrective actions have been taken by the Administration, including any sanctions that have been assessed against plans where such complaints have been filed?

Once this data is compiled, I ask that the information requested in this letter be posted monthly on the Medicare Web site in an area easily accessible by Medicare beneficiaries, providers, and the general public. Continual updating of this information and the ability to track it over time will be an important tool in our evaluation of Part D.

Answer:

CMS takes its responsibilities for monitoring and enforcing plan compliance with Part D program requirements very seriously. Our aggressive oversight of prescription drug plan sponsors has resulted in well over a thousand compliance actions this year. Specific examples of compliance activities in the marketing area since last year relate to agent misrepresentations or other misconduct, marketing prior to October 1, 2005, use of unapproved marketing materials, and enrollment systems failures. CMS uses the full range of available enforcement tools in pursuing plan compliance with Medicare program requirements. This includes issuing numerous corrective action plans and compliance warning letters. Usually, these steps lead to prompt, responsive actions by plans. However, where necessary to achieve compliance, CMS will levy civil monetary penalties and implement intermediate sanctions such as freezing marketing and enrollment. Where necessary, we will also terminate plans.

CMS' compliance and enforcement program emphasizes analysis of complaints and plan-reported data, along with routine and focused program compliance audits. We are structuring the audits in a way that ensures independence and unbiased objectivity. We have and will continue

to consider information on plan performance annually as we make contracting decisions for future years – including decisions on 2007 contracts.

CMS has publicly released sponsor-level data about complaints it has received regarding Part D plans. These data are available on the CMS website at http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1905. Most of these complaints are about enrollment or disenrollment in a plan, when beneficiaries start or stop using coverage, reflecting one-time issues in "getting connected" to a plan. A smaller share of complaints concern difficulties that beneficiaries have in getting needed drugs or plan customer service. On average these rates are below one per 1,000 beneficiaries. Very few beneficiary complaints involve other issues like problems with the exceptions or appeals process.

The Honorable Jim Davis
Questions for Dr. Mark McClellan, Administrator
The Centers for Medicare and Medicaid Services
March 1, 2006
Subcommittee on Health
Hearing entitled: "Medicare Part D: Implementation of the New Drug Benefit"

Question:

I have learned that many pharmacists are simply not getting reimbursed by Part D drug plans. In some cases, this problem is forcing pharmacists to take such drastic measures as closing their doors to all Medicare beneficiaries. For example, in my home state of Florida, Carrabelle Medical Pharmacy, a community pharmacy in the Panhandle and the only one in town, will begin turning away Medicare patients next month because HMO plans are not paying promptly and in some cases not paying at all. Carrabelle Medical Pharmacy also services the Assisted Living Facility, which will now have to go to the next town, 45 minutes away, in order to get their Medicare beneficiary's medications.

CMS has the authority to sanction any Part D plan for failure to comply with contract requirements. Sanctions can include a written notice of warning, suspension of enrollment of Medicare beneficiaries, suspension of Medicare payments and suspension of plan marketing activities. Has CMS taken any of these steps in cases where HMO companies have not reimbursed pharmacies? If not, why not?

Answer:

CMS has investigated a number of complaints from pharmacists, including complaints that they have not been paid in a timely manner. The result of the vast majority of these investigations has been that the plan has paid the pharmacy in accordance with the terms of its contract. We would be happy to follow-up on any specific concerns that Carrabelle Medical Pharmacy may have regarding plan compliance with the terms of their contract.

Question:

The Medicare program usually has prompt payment guidelines. Why has CMS not established some minimum guidelines for Medicare Part D to protect patient access to pharmacies?

Answer:

While Congress explicitly addressed prompt payment of claims by MA plans (see section 1857(f) of the Act and 42 CFR 422.520), no similar provision exists under Medicare Part D. As we have stated in the past, outside of the minimum performance and service criteria, Part D sponsors and pharmacies may propose a number of contracting terms and conditions. With rare exceptions, CMS does not generally involve itself in determining whether such contracting terms

are acceptable, since these are fact-specific questions that are best left between negotiating parties.

In response to pharmacists concerns about plans paying promptly, CMS examined contracts for the leading PDPs and determined that most contracts provide for payment to pharmacies within 30 days. Thus, payment within 30 days of the first claim submitted in a billing cycle appears to be the "industry standard" accepted by most contracting pharmacies. This industry standard appears to be a "minimum guideline" that has already been established by the competitive marketplace. Additionally, it is consistent with the minimum payment terms CMS established for MA plans pursuant to 42 CFR 422.520.

Question:

Some pharmacists have dispensed drugs to Medicare beneficiaries at no charge when, due to computer malfunctions, inaccurate information, etc., they could not determine which drug plan to bill. Some of these pharmacies are facing rejection and unpaid claims from drug plans for these expenditures. What specific steps will CMS take to facilitate prompt and accurate reimbursement to pharmacies for these expenditures?

Answer:

Because implementation challenges delayed payment of claims or verification of beneficiary eligibility for a percentage of Medicare enrollees, CMS has instructed plans that their typical window for submission of claims by pharmacies must be expanded. Ordinarily plans have a time period of between 30 and 90 days during which a pharmacy can submit claims. We have required plans to expand that to 180 days for claims incurred during the first half of the year in recognition of the fact that pharmacies may not have been able to obtain appropriate or adequate billing information even though they have dispensed medications to meet their patients' needs.

For beneficiaries who were for any time covered by two different plans, CMS is facilitating plan-to-plan reconciliation of claims paid, so that pharmacists will not have to resubmit claims or sort out issues of coverage once the beneficiary's coverage status is resolved. CMS has also developed a process for state-to-plan reconciliation for claims incurred by States and State Pharmaceutical Assistance Programs between January 1 and March 31 2006 which provided coverage to dual eligible and other low-income subsidy eligible individuals through state payment systems – again providing an alternative process for recouping costs that avoids pharmacies having to reverse and re-bill claims.

Question:

One of the most difficult transitions in the Part D benefit has been the transition of low income beneficiaries, who previously had prescription drug coverage under Medicaid, to the Part D benefit. For these dual eligibles, the new benefit was not voluntary, and many dual eligibles are having to pay more than they previously paid for more restrictive coverage.

How are dual eligible beneficiaries faring in terms of accessing needed medicines? Specifically, can you tell me, with respect to enrollment to dual eligibles under Part D:

a) the number of auto-enrolled duals who subsequently switched plans;
b) the number of dual eligibles whose plan does not cover at least one medicine they are taking;
c) the number of appeals filed on behalf of dual eligibles to access a non-covered or otherwise restricted drug the number of successful appeals; number of denials; and number of requests still pending.

Answer:

a) Of the approximately 5.7 million dual eligible beneficiaries auto-enrolled into Medicare prescription drug plans, 1.3 million have subsequently changed Part D plans into a plan of their own choosing.

b) MMA requires CMS to review Part D formularies to ensure that beneficiaries have access to a broad range of medically appropriate drugs to treat all disease states and to ensure that the formulary design does not discriminate or substantially discourage enrollment by certain groups. CMS has ensured that prescription drug plans offer a comprehensive array of drugs that reflects best practices in the pharmacy industry as well as current treatment standards. Our goal is to ensure beneficiaries receive clinically appropriate Part D medications at the lowest possible cost. The minimum statutory requirement is that a formulary must include at least two drugs in each approved category and class (unless only one drug is available for a particular category or class), regardless of the classification system that is utilized. For some conditions, such as mental illness, cancer and HIV/AIDS, all or substantially all of the drugs must be covered. Even if a plan's formulary does not cover the Part D drug a Medicare beneficiary takes, it will cover similar drugs that are also used to treat that condition. Finally, a beneficiary can request an exception to receive an off-formulary Part D drug, if the on-formulary drugs would not be as effective or would have adverse effects, or both. So, all Medicare beneficiaries, including those dual eligible beneficiaries, have access to medically appropriate drugs.

c) We are unable to answer this question at this time because available appeals data is not broken down by beneficiary type.

Question:

Many of the Medicare beneficiaries residing in assisted living facilities are frail, elderly individuals who require the same specialized pharmacy services as residents of other long-term care facilities. Assisted living residents should therefore receive the same protections that CMS has extended to other long-term care residents, including special enrollment periods and exemption from cost-sharing requirements. Does CMS plan to include assisted living facilities in the regulatory definition of "long-term care facilities"?

Answer:

We understand your concerns regarding the imposition of cost sharing on full benefit dual eligibles who are residents of assisted living facilities. Unfortunately, based on the specific statutory language in the MMA, we do not believe we have latitude to treat beneficiaries in assisted living facilities as institutionalized for the purpose of cost sharing exemption.

Section 1860D-14(a)(1)(D)(i) of the Social Security Act waives cost sharing for full benefit dual eligibles under the Medicare prescription drug program who meet the definition of an institutionalized individual in section 1902(q)(1)(B) of the Act. Section 1902(q)(1)(B) of the Act defines an institutionalized individual as someone who is an inpatient in a medical institution or nursing facility "for which payments are made under the Medicaid program" throughout a month, and who is determined to be eligible for medical assistance under the State plan. An inpatient is someone who, on the recommendation of a physician or dentist, has been admitted to a medical institution or nursing facility, and is expected to, or actually does, receive room, board and professional services for longer than 24 hours. A "nursing facility" is one type of long term care facility and is distinct from an "assisted living facility." The term "medical institution" is broader, and may include facilities such as assisted living facilities, but payment under Medicaid is only available for specified inpatient settings. Assisted living facilities are not so specified. Thus, an assisted living facility is not an impatient setting "for which payments are made under the Medicaid program." Since no Medicaid payment is available for assisted living facilities, individuals in such facilities do not meet the general definition of an institutionalized individual as specified in 1902(q)(1)(B). That said, we would like to work with you and your state to address ways to provide help with prescription drug copayments for vulnerable beneficiaries in home and community based settings.

Question:

A report on dual eligibles in Connecticut found that the out of pocket costs for a person with HIV/AIDS automatically enrolled in a plan varied from $300 per year to $4,773 per year. For a beneficiary with schizophrenia, out of pocket costs varied from $228 to $1,033 per year depending on plan enrollment.

A study by the HHS Inspector General found that nationally nearly a third of dual eligibles were assigned to plans that covered less than 85 percent of the drugs most commonly used by this population.

Given this wide variety of out of pocket costs and coverage, it seems critical that CMS work with the states and other partners to ensure dual eligibles are put in plans that cover their medicines at the lowest possible cost. Dual eligibles are being auto-enrolled into plans which have premiums that are at or below the benchmark premium. Why would we subsidize a plan that doesn't provide the right drugs for a person or charges them too much? How does CMS plan to ensure that this problem doesn't continue in the future and that dual eligibles are enrolled in the plan with the lowest out of pocket costs?

Answer:

Beginning January 1, 2006, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) makes prescription drug coverage available to all 43 million Medicare beneficiaries, including the approximately 6 million low-income beneficiaries who also are enrolled in Medicaid. These dual eligible beneficiaries will receive comprehensive coverage at little or no cost.

As you know, full-benefit dual eligibles had the opportunity to join a Medicare prescription drug plan in their area once enrollment began on November 15, 2005. However, if they took no action on their own, CMS enrolled them in a Medicare prescription drug plan effective January 1, 2006 to ensure there is no lapse in prescription drug coverage. The MMA required CMS to randomly auto-enroll full benefit dual eligible beneficiaries into prescription drug plans below the benchmark. While assignment to prescription drug plans had to be random, all prescription drug plans are required to have robust formularies. By law, all Medicare drug plans must cover all medically necessary Part D treatments. In most classes, at least two drugs are covered. For some conditions, such as mental illness, cancer and HIV/AIDS, all or substantially all of the drugs must be covered. Even if a plan's formulary does not cover the drug a Medicare beneficiary takes, it will cover Part D drugs that are also used to treat that condition. So, all Medicare beneficiaries, including those dual eligible beneficiaries, are in plans that cover drugs that also are used to treat their condition. For example, many drugs treat stomach acid or cholesterol or hay fever, so even if a plan doesn't cover one drug, it will cover a drug that is similar. However, if a dual eligible beneficiary is not enrolled in plan that best meets their needs, they have the unique opportunity to switch plans at any time. Additionally, CMS has partnerships with various organizations, such as Access to Benefits Coalition, which help low-income beneficiaries evaluate options and under the new prescription drug coverage.

The Honorable Frank Pallone, Jr.
Questions for Dr. Mark McClellan, Administrator
Centers for Medicare & Medicaid Services (CMS)
March 1, 2006
Subcommittee on Health
Hearing entitled: "Medicare Part D: Implementation of the New Drug Benefit"

New Jersey has spent approximately $86 million in Medicare-related drug claims for beneficiaries enrolled in its State Pharmacy Assistance Program (SPAP). New Jersey is seeking reimbursement for the portion of the claims that should have been paid out by participating Medicare prescription drug plans. I would like for Dr. McClellan to respond to the following questions:

Question:

Will the current demonstration project be amended to include reconciliation for the non-LIS SPAP claims?

Answer:

We very much appreciate the efforts States have made during this transition period in ensuring that dual eligible beneficiaries and other low-income subsidy entitled beneficiaries receive the prescription medication they need. As you know, through a Medicare demonstration project, developed in consultation with State Medicaid Directors, States that have assisted their dual eligible beneficiaries and low-income subsidy entitled populations in obtaining and accessing Medicare Part D coverage will be reimbursed for their efforts. In particular, the demonstration permits Medicare payment to be made to States for amounts they have paid for a dual eligible's part D drugs, or a low-income subsidy entitled Part D plan enrollee's Part D drugs, to the extent that those costs are not otherwise recoverable from a Part D plan and are not the Medicare beneficiary's cost sharing requirement. In addition to providing Medicare funds to reimburse amounts paid by States for Part D drugs, the demonstration would also provide payments for certain administrative costs incurred by States. The demonstration does not include reconciliation for non-LIS SPAP claims, and there are no plans to amend it to do so.

Question:

Will a separate demonstration project be established?

Answer:

There are no plans to establish a separate demonstration.

Question:

Will CMS facilitate claims reconciliation between the private prescription drug plans and States for non-LIS SPAP beneficiaries in the same fashion they plan to for dual eligibles under the demonstration project?

Answer:

As noted, the demonstration project permits Medicare payment to be made to States for amounts they have paid for a dual eligible's Part D drugs, or a low-income subsidy entitled Part D plan enrollee's Part D drugs, to the extent that those costs are not otherwise recoverable from a Part D plan and are not the Medicare beneficiary's cost sharing requirement. While the State of New Jersey's costs for their beneficiaries not eligible for the low-income subsidy cannot be included as part of the demonstration, the state does have an avenue to recover reimbursement for the payment of Part D costs they have incurred for their beneficiaries. Consistent with the coordination of benefit (COB) requirements implemented under the regulation at 42 CFR 423.464(b), Part D plans will be required to reimburse SPAPs, just like any other provider of prescription drug coverage, when the plan should have paid primary. We therefore encourage the state to work directly with the Part D plans to recover amounts owed.

Question:

Will CMS pay any difference between the amount that should have been covered by the private plans and what was actually paid by the State?

Answer: Through the demonstration CMS will reimburse States for amounts they have paid for a dual eligible's part D drugs, or a low-income subsidy entitled Part D plan enrollee's Part D drugs, to the extent that those costs are not otherwise recoverable from a Part D plan and are not the Medicare beneficiary's cost sharing requirement.

Question:

What time frame can New Jersey expect to be reimbursed for non-LIS SPAP drug claims that should have been paid for by private plans?

Answer:

As mentioned above, consistent with the coordination of benefit (COB) requirements implemented under the regulation at 42 CFR 423.464(b), Part D plans will be required to reimburse SPAPs, just like any other provider of prescription drug coverage, when the plan should have paid primary. We therefore encourage the state to work directly with the Part D plans to recover amounts owed. The specific time-frames for reimbursement will vary by prescription drug plan.

Part D Exceptions and Appeals

Question:

I would like CMS to provide some data on Part D exceptions and appeals. If the data does not exist, please indicate so, and specify when the data might become available. Do you have data on the following items under Part D?

a. The number of requests for exceptions and appeals under Part D that have been filed with private plans to date;

b. The types of exceptions and appeals filed, including non-formulary, step therapy, quantity limits, not medically necessary, out-of-network, etc;

c. The disposition of those requests (how many in favor of the beneficiary, how many in favor of the plan);

d. The number of requests that are still pending/unresolved, and the number which have not been resolved within CMS' required time frames; and

e. The number of requests patients have pursued to the next higher level.

I would like to know this data both for the stand-alone drug plans and for the other private plans (e.g. Medicare advantage plans, PPOs, etc., offering a drug benefit).

Answer:

CMS is committed to providing information about plan performance to ensure beneficiaries can make informed decisions about plan selection. While we were unable to provide data regarding beneficiary appeals and exception requests at the time of this hearing, we subsequently released comprehensive appeals and exceptions data for January 1, 2006 through July 31, 2006. These data include the overall volume of reconsideration requests, including standard cases and expedited cases; the types of appeals received (i.e., utilization management disputes, off-formulary exception requests, cost-sharing disputes, tiering exception requests); the overall rate of reverals by the Part D QIC; reversal rates by appeal type; and the overall timeliness of reconsideration cases. The complete fact sheet that sets forth data in each of these areas is copied below, and also available on the CMS website at http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1972 .

FACT SHEET
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The following data summarizes and highlights some of the key data on reconsiderations since the inception of the Medicare prescription drug benefit program on January 1, 2006.

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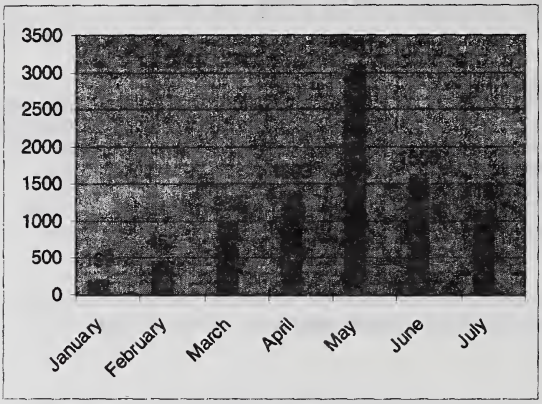
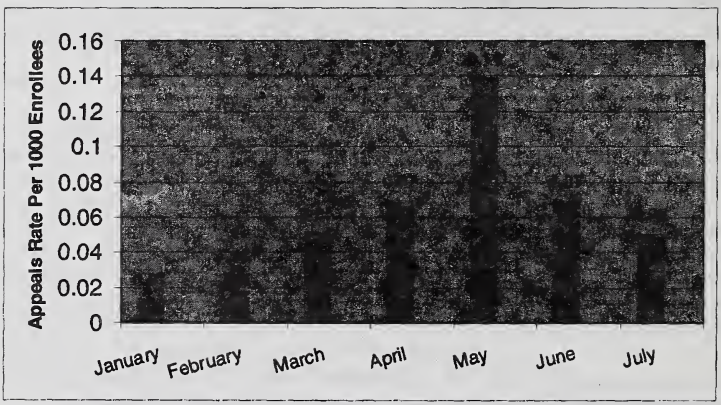
Number of appeals received by the Part D QIC by month:



Rate of appeals received by the Part D QIC by month:[3]



[3] Monthly appeals rate was calculated using the enrollment at the end of each month.

Types of Appeals

Of the 8,336 appeals decided through July 31, 2006:

36% involved a drug utilization management tool dispute and represents 0.15 drug utilization appeals for each 1000 beneficiaries enrolled.

34% involved an off-formulary exception request and represents 0.14 off-formulary exceptions appeals for each 1000 beneficiaries enrolled.

26% involved a non-Part D drug (a drug that is statutorily excluded) request and represents 0.11 non-Part D drug requests for each 1000 beneficiaries enrolled.

2% involved a cost-sharing dispute and represents 0.01 cost-sharing dispute appeals for each 1000 beneficiaries enrolled.

<2% involved a tiering exception request and represents 0.01 tiering exceptions appeals for each 1000 beneficiaries enrolled.

<1% involved out-of-network pharmacy coverage.

Overall Reversal Rate

Excluding cases that were dismissed, withdrawn, or remanded (the Part D QIC did not have jurisdiction to make a substantive decision on the case) and cases involving non-Part D drugs, the Part D QIC reversed plan decisions in 42% of cases.[4]

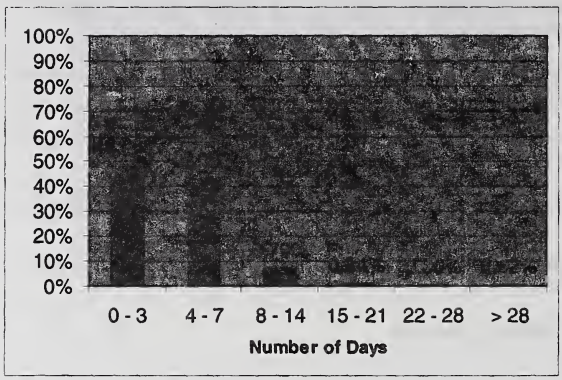
Reversal Rates by Appeal Type[5]

Drug utilization management tool dispute	51%
Off-formulary exception request	31%
Non-Part D drug	15%
Tiering exception request	33%
Cost-sharing dispute	33%
Out-of-network pharmacy coverage	60%

[4] In comparison, the reversal rate for Part A cases was 24% and for Part B cases was 39% for the same period. The reversal rate for Part C cases during this period was 13%. Note that the reversal rate for Part C is impacted by the fact all adverse Medicare Advantage plan decisions are automatically forwarded to the Part C QIC.
[5] Calculation of the reversal rate by appeal type excludes cases that were dismissed, withdrawn or remanded.

Overall Timeliness of Reconsideration Cases

Distribution of decided appeals by process days for all reconsideration cases:



The Honorable Chip Pickering
Questions for the Honorable Mark B. McClellan, M.D., PhD., Administrator
Centers for Medicare and Medicaid Services
March 1, 2006
Subcommittee on Health
Hearing entitled: "Medicare Part D: Implementation of the New Drug Benefit"

Question:

It is clear that CMS's regulations interpreting the Part D statute leave significant gaps in coverage for home infusion therapy. Many beneficiaries who require an infusion drug - antibiotic therapy, for example - and who could otherwise benefit from the availability of home infusion are not getting access to infusion in the home because CMS has not allowed coverage of the supplies, equipment, and services necessary to safely administer the therapy. Instead, these people have to obtain infusion therapy in hospitals and nursing homes, which obviously is more expensive than homecare.

Several situations in my home state of Mississippi have been brought to my attention that display this problem of patients who have Medicare Part D coverage for the medication, but the supplies that are used to administer the medication intravenously are not a covered benefit under the Part D plan.

What does CMS intend to do to address this access issue?

Answer:

Part D plans may only cover the ingredient cost, not supplies, equipment, or professional services related to home infusions therapy. Because the Part D benefit does not cover the costs for the supplies, equipment, or professional services, such costs should be paid for by the same payor as in 2005. We are working with the plans, the states, and the Home Infusion industry to streamline this process and coordinate services.

The Honorable Henry A. Waxman
Questions for Dr. Mark McClellan, Administrator
Centers for Medicare & Medicaid Services (CMS)
March 1, 2006
Subcommittee on Health
Hearing entitled: "Medicare Part D: Implementation of the New Drug Benefit"

Assets Test

Dr. McClellan, I think one of the biggest disappointments we all have is the failure to enroll in the program more of the low-income subsidy-eligible people. As you know, these are people who are not automatically enrolled as the dual eligibles are, but they are people of very low income who need this benefit.

Yet the statistics seem to indicate that about half of the people contacted by Social Security as potentially eligible to receive this help are then determined to be ineligible. I believe it is widely recognized that the assets test is the culprit here. Either some technicality of the test blocks people, or they don't have the information to reply to the questions, or it simply discourages them. How many people have the cash value of their life insurance policy at their fingertips, for example?

The fact is that people at this low-income level are very unlikely to have significant assets. Removing this barrier would surely be a significant step to increasing the enrollment of the very low-income population that clearly would get a good deal if they were enrolled in the prescription drug benefit.

Question:

Can you provide statistics indicating the percentage of individuals who have been contacted by Social Security who are then determined ineligible? Can you provide additional details and statistics indicating the reason that these individuals have been determined to be ineligible?

Answer:

The Social Security Administration (SSA) was given authority to process low-income subsidy applications and to make extra help eligibility determinations for individuals who were not automatically eligible. As of June 2, 2006 SSA announced that over 5.1 million people have applied for the extra help. SSA has processed almost 5.0 million cases (about 98 percent of applications) of these, almost 875,000 did not require a decision because the applicant was deemed eligible or filed a duplicate application. Of the remaining 4.1 million applicants, over 1.85 million or approximately 45 percent were found to be eligible for the extra help. The rest were ineligible because of excess income and/or resources.

Question:

Can this issue be solved administratively? If so, please provide describe CMS actions to solve this problem.

Answer:

The statute defines a subsidy eligible individual (1860D-14(a)(3)(A)) as a part D eligible individual who:

(i) is enrolled in a prescription drug plan or MA-PD plan;
(ii) has income below 150 percent of the poverty line applicable to a family of the size involved; and
(iii) meets the resources requirement described in subparagraph (D) or (E).

Therefore, there is no administrative flexibility to change the low-income subsidy eligibility standards, including the resource test.

Question:

Has the Administration suggested changing the law? Would you support Congressional action to eliminate the assets test?

Answer:

The Administration has not suggested changing the asset test. We are pleased that over 38 million Americans--90 percent of people with Medicare are now receiving comprehensive prescription drug coverage, including 10 million beneficiaries receiving the benefits of the low-income subsidy.

CMS Oversight of Plans

I am interested in the level of oversight that CMS undertook to screen drug plans at the point of application, and your continuing oversight work.

Question:

Would you provide us with the number of plans that applied to CMS, and the number that you turned down for participation in the program?

Answer:

Ninety-eight potential stand-alone prescription drug plan (PDP) contractors applied for the 2006 contract year. Sixteen of these potential contractors withdrew during the

process. Thirty-eight of the contractors were issued Notices of Intent to Deny. All of these except for 1 contract ultimately cured their applications. At the end of the process we had 81 approved PDP contracts (excluding Medicare Advantage plans and employer plans) for 2006.

Question:

Did you turn down plans because you determined that their premiums were too high or could not be justified? How many? Please provide detailed information on why these plans were turned down.

Answer:

CMS does not turn down plans based on their premiums. Rather, CMS reviews an organizations' bid submission for a Part D plan offering to determine the reasonableness of the organizations' actuarial assumptions/methods. While an organization's Part D bid forms the basis of specific plan premiums, CMS does not reject plans based on predetermined premium thresholds.

Question:

Does the Administration have any reason to believe that low premiums were being used as "loss leaders" to get people enrolled in plans and either retain them — even in the face of large premium increases in 2006 – through inertia, or switch them to more profitable Medicare Advantage plans?

Answer:

We do not at this time.

Question:

Plans have been involved in extensive promotional activities since November 2005. CMS has been responsible for oversight of these plans during this time period.

Please provide me with detailed statistics on the number of oversight actions (including warnings, fines, or any other CMS actions) taken against plans by CMS since November 2005. Please include information on the name of the plan, the plan provider, the date of the action, the type of action, and the reason for the action.

Answer:

Medicare's oversight actions begin with direct contacts with drug plans, which usually result in resolution of the problem. In cases where this action does not lead to timely

resolution, Medicare follows up with a formal notice to the plan. As of May 2006, Medicare had issued:

· 651 warning letters to plans, for topics such as posting errors on the Medicare Personal Plan Finder;

· 152 notices of potential non-compliance, for topics including failure to meet call center performance requirements, particularly in the early months of the program; and

· 318 requests for specific business plans, on topics such as improving call center performance and the submission of correct information for the Medicare Personal Plan Finder.

In most cases, these compliance actions led drug plans to resolve the problem. In cases where the plan does not effectively resolve the issue, Medicare has taken further enforcement action. These actions include:

· Temporarily restricting plan marketing by removing information about the prescription drug plan from the Personal Plan Finder. As of May 2006, Medicare had taken such action on 75 occasions, including cases when plans continued to provide incorrect information about drug prices and formularies. Examples include failing to include required drugs in the plan formulary lists, and restricting access to certain drugs in circumstances where utilization management is not allowed (for example, utilization management restrictions on certain drugs for HIV/AIDS). These actions to "suppress" plan marketing resulted in plans taking action to correct the compliance problem.

· Imposing a corrective action plan (CAP) on one plan when other compliance steps were not effective. This Medicare Advantage prescription drug plan was required to submit the corrective plan to assure access to "transitional" coverage of all current medications for new enrollees.

· Pursuing the termination of an organization's prescription drug plan and Medicare Advantage plan contracts, for a persistent pattern of failure to comply with Medicare requirements.

Question:

It will also be critical that you have extensive oversight of future activities. If plans propose to increase premiums or prices, what information will you require before they can do so?

Answer:

2006 plan sponsors will be required to submit new bids for their 2007 benefit options. Bids will be reviewed pursuant to established CMS procedures for evaluating actuarial

soundness, and are subject to negotiation pursuant to the authority granted CMS by the MMA.

Question:

How will you determine whether it is accurate and the change is justified?

Answer:

2006 plan sponsors will be required to submit new bids for their 2007 benefit options. Bids will be reviewed pursuant to established CMS procedures for evaluating actuarial soundness, and are subject to negotiation pursuant to the authority granted CMS by the MMA.

Question:

Other issues will also require extensive oversight. How are you monitoring their performance in making timely payments to the pharmacies in their network?

Answer:

CMS has investigated a number of complaints from pharmacists that they have not been paid in a timely manner. CMS also conducted a survey of plans participating in Medicare Part D to obtain up-to-date information on how Part D contractors are making payments to their network pharmacies. The survey found that all of the top 20 PDPs have a billing cycle of 15 days or less. Indeed, 8 of the top 20 PDPs reported an even shorter billing cycle of 7 to 10 days. This information is critical insofar as plans' billing cycles are an important factor in the timeliness of pharmacy payments.

More importantly, however, the vast majority of PDPs have contract terms that pay pharmacies within 30 days of the first day of the billing cycle, and all PDPs have contract terms that generally lead to payment within 30 days.

Question:

Does CMS consider it its responsibility to assure reasonably timely payments?

Answer:

Resolving specific pharmacy complaints is a top priority for CMS. For this reason, we have investigated a number of complaints from pharmacists that they have not been paid in a timely manner. The result of the vast majority of these investigations has been that the plan has paid the pharmacy in accordance with the terms of its contract. Where mistakes were discovered (e.g., a plan sending a check to the wrong address or to the pharmacy's claims payment representative, such as a pharmacy buying group or Group

Purchasing Organization), the plans quickly remedied any problems to ensure pharmacies are paid as expeditiously as possible.

Question:

What does CMS consider "timely payment" to be?

Answer:

CMS conducted a survey of plans participating in Medicare Part D to obtain up-to-date information on how Part D contractors are making payments to their network pharmacies. The vast majority of PDPs have contract terms that pay pharmacies within 30 days of the first day of the billing cycle, and all PDPs have contract terms that generally lead to payment within 30 days. Outside of Medicare, payment within 30 days is largely the industry standard, indicating that the payment timelines in Medicare a comparable to or better than those that exist elsewhere in the health insurance industry.

Question:

How will you monitor the plans' volume limits, step therapy requirements, or other prior approval requirements that put administrative barriers in the way of getting the drugs that physicians prescribe? Will you judge whether these barriers are designed in a way that disadvantages certain kinds of patients, for example? Will you be sure that requirements, like step therapy, are not resulting in the denial of drugs to patients that should be available to them under all plans?

Answer:

Formularies and formulary management practices vary across plans, subject to CMS-published guidelines reflecting two overarching requirements in the MMA. First, Part D plan sponsors must provide access to medically necessary treatments and must not discriminate against any particular types of beneficiaries. Second, plan sponsors are expected to use approaches to drug benefit management that are proven and in widespread use in prescription drug plans today.

As a condition of participation in Part D, sponsors must submit their plan formularies for CMS review and approval. CMS reviews plan formularies using a 13-step process, which considers covered drugs as well as utilization management techniques. The formulary guidelines describe 13 review checks to ensure that formularies meet all statutory and regulatory requirements.

If CMS reviewers find that a plan's formulary design in any one of these areas could discriminate against certain types of beneficiaries or otherwise violate Part D program requirements, that formulary will not be accepted and if unchanged, the plan is not eligible for a Part D contract.

In the case of the six therapeutic categories or classes of drugs for which plans must include "all or substantially all" available drugs, CMS has found plan sponsors are complying with the formulary guidance. Prior authorization may appropriately apply to these drugs, consistent with FDA clinical and safety guidelines. CMS has worked with industry partners to develop standardized prior authorization and appeals forms to facilitate consistency across plan sponsors.

Beneficiaries may request an exception to have a non-formulary drug treated as on-formulary under a particular plan, or to access a particular drug on a plan's formulary at a more favorable cost-sharing level. An exception is a type of coverage determination request. All Medicare drug plan sponsors must have a timely and efficient process for making coverage determination decisions, including decisions on exception requests. Generally, plan sponsors must approve exceptions when they find that the drug is medically necessary, consistent with the supporting information provided by the member's doctor.

Question:

How will you monitor performance in responding in a timely manner to appeals? What will be your standard to decide whether a plan's performance is unacceptable?

Answer:

Medicare prescription drug plans are subject to a number of statutory, regulatory and contractual requirements that hold them accountable to CMS for a wide variety of policies and actions. Additionally, CMS has communicated its expectations for complying with many statutory and regulatory requirements through comprehensive guidance documents (e.g., focusing on enrollment, appeals and grievances, and plan oversight to name just a few).

CMS has a team of plan contract managers who are in constant communication with the plans to assure that any performance problems – and particularly those impacting beneficiaries or providers – are addressed quickly. If the problems persist, they are referred to senior level CMS people who work with senior level plan managers to reach resolution. In rare cases, plans are asked to work with CMS to develop a formal corrective action plan. CMS can elect not to renew a plan's contract for significant performance shortcomings.

Rebates

Under the law, information on the amount of the rebates and other discounts insurers negotiate with drug companies is not publicly available, but CMS has access to that information. You are able to determine the size of the rebate, and what portion of the

rebate is, in fact, passed on to the beneficiaries. You are, by law, supposed to determine that a significant portion of the rebate is, in fact, returned, and that beneficiaries have "access" to negotiated prices at all points in the benefit cycle.

Question:

Has CMS developed a definition of "significant" for the purposes of this provision? Have you informed plans of it? Please describe this definition in detail.

Answer:

The Medicare Modernization Act (MMA) at 1860D-2(d)(1)(B) states that "For purposes of this part, negotiated prices shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs, and include any dispensing fees for such drugs." We have interpreted this section of the MMA as requiring Part D plans to pass on to enrollees some, but not necessarily all, of these price concessions.

We believe that market competition will encourage Part D plans to pass through to enrollees a high percentage of the negotiated price concessions they obtain in the form of negotiated prices at the point of sale. Establishing minimum threshold levels for the pass-through of negotiated price concessions would have the effect of undercutting market competition, as Part D plans might cluster their negotiated prices around that threshold.

Question:

Please provide information indicating the size of the manufacturer rebates and discounts that plans are reporting to CMS, and the extent to which these rebates and discounts are being passed on to consumers. To the extent possible, please provide a separate detailing of discounts obtained from pharmacists, and the extent to which these are being passed on to consumers.

Answer:

Section 1860D-2(d)(2) of the MMA requires Part D plan sponsors to "disclose to the Secretary (in a manner specified by the Secretary) the aggregate negotiated price concessions described in paragraph (1)(B) made available to the sponsor or organization by a manufacturer which are passed through in the form of lower subsidies, lower monthly beneficiary prescription drug premiums, and lower prices through pharmacies and other dispensers." CMS has not yet begun collecting this information from the plans, as we are still in the first few months of the benefit, and therefore cannot provide this information at this time.

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